

US3762161 (Prod: Wake Forest University Health Sciences)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:43:36

All time stamps listed in this document are displayed in GMT

US3762161

Form: Participant Creation

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

[Participant ID](#)

US3762161

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

US3762161

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SCRN

US3762161

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Date of Informed Consent (*dd MMM yyyy*) 02 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 23:06:11

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	CATARACTS - BILATERAL
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	DIABETES
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	NUMBNESS IN FEET
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 (5)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	TREMORS
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	DIABETIC NEUROPATHY IN FEET AND LOWER LEGS
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	STROKE - CEREBELLUM
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 (8)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	HEART ATTACK
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	KIDNEY STONES
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 (10)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	CARDIOVASCULAR ARTERIAL BYPASS GRAPH
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN AUG 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:22 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 14:22
Height (<i>xxx.x</i>)	68 in
Weight (<i>xxx.x</i>)	205 lb
BMI (<i>xxx.x</i>)	31.23532 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) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:06:11

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 23:06:11

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 189561

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 23:06:11

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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)	02 SEP 2020
Time of assessment (00:00-23:59)	14:22 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 14:22
Temperature (xxx.x)	97.0 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)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 15:50
Temperature (xxx.x)	97.4 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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 15:12 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 15:12

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 SEP 2020

Collection time (00:00-23:59)

14:59 (24 HR)

Collection date and time (derived)

02 SEP 2020 14:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:55	02 SEP 2020 14:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 15:55

PC Open Date & Time

02 SEP 2020 15:32

PC Close Date & Time

02 SEP 2020 18:02

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

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 02 SEP 2020 18:57

PC Close Date & Time 03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 21:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 21:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

06 SEP 2020 22:53

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:40

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

02 SEP 2020 15:56

PC Open Date & Time

02 SEP 2020 15:32

PC Close Date & Time

02 SEP 2020 18:02

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

02 SEP 2020 18:57

PC Close Date & Time

03 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

03 SEP 2020 14:33

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

04 SEP 2020 21:08

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

05 SEP 2020 21:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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

06 SEP 2020 22:54

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

07 SEP 2020 21:40

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

08 SEP 2020 22:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 15:58
PC Open Date & Time	02 SEP 2020 15:32
PC Close Date & Time	02 SEP 2020 18:02

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 18:57

PC Close Date & Time

03 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:09
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

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)

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:59
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

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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US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 22:54
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

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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US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:41
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

63 of 3129

EAB) (1725)

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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)	30 SEP 2020
Time of assessment (00:00-23:59)	15:13 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 15:13
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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)	30 SEP 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:20
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 15:30 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 15:30

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

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

15:16 (24 HR)

Collection date and time (derived)

30 SEP 2020 15:16

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:26	30 SEP 2020 15:26
Nasopharyngeal Swab 2	No		

US3762161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 16:27

PC Open Date & Time

30 SEP 2020 15:50

PC Close Date & Time

30 SEP 2020 18:20

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.2 °F

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

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

PC Time Stamp	30 SEP 2020 23:04
PC Open Date & Time	30 SEP 2020 19:15
PC Close Date & Time	01 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 02:29

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 22:54

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

97.3 °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

03 OCT 2020 23:07

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 21:16

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 09:43

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

06 OCT 2020 21:30

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

30 SEP 2020 16:27

PC Open Date & Time

30 SEP 2020 15:50

PC Close Date & Time

30 SEP 2020 18:20

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

30 SEP 2020 23:05

PC Open Date & Time

30 SEP 2020 19:15

PC Close Date & Time

01 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

02 OCT 2020 02:30

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

7

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

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 22:59

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 23:08

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 21:17

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

06 OCT 2020 09:44

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 21:30

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 16:28
PC Open Date & Time	30 SEP 2020 15:50
PC Close Date & Time	30 SEP 2020 18:20

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 23:05
PC Open Date & Time	30 SEP 2020 19:15
PC Close Date & Time	01 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 02:31
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 22:59
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 23:08
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

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)

105 of 3129

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 21:17
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

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)

107 of 3129

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 09:44
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 ☒

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:31
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	VISIT3

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	09:41 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 09:41
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

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.

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 NOV 2020

Collection time (00:00-23:59)

10:03 (24 HR)

Collection date and time (derived)

03 NOV 2020 10:03

US3762161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 23:06:11

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 22:42:24
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 NOV 2020 11:24:14
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 00:18:17

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 DEC 2020 18:54:30
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 DEC 2020 12:00:42
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 21:34:50

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 19:49:38
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 00:06:01
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 02:34:42
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

29 JAN 2021 21:26:54

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 FEB 2021 01:31:40

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 FEB 2021 12:06:42

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

19 FEB 2021 17:10:45

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

27 FEB 2021 05:37:26

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

05 MAR 2021 00:04:20

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 MAR 2021 13:11:55
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

19 MAR 2021 12:44:13

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

26 MAR 2021 11:58:07

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

04 APR 2021 02:42:20

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	09 APR 2021 18:51:41
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

16 APR 2021 12:50:50

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

23 APR 2021 16:02:59

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

30 APR 2021 16:47:40

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 257

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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°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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	05 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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="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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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13 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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°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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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 <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"/>

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3762161

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:43:36

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		01 APR 2021 10:17:09

US3762161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 18:32:20

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 18:32:20

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3762161

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3762161

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

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.

US3762161

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 APR 2021

Collection time (00:00-23:59)

09:20 (24 HR)

Collection date and time (derived)

1 APR 2021 09:20

US3762161

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:34:25

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3762161

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

Date of Contact	9 NOV 2020
Time of Contact	14:25
Date and Time of Contact (derived)	9 NOV 2020 14:25
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>

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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"/>

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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	9 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.4 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 type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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"/>

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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"/>

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		345 of 3129
EAB) (1725)		

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" 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 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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 ☐

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Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

Date of Visit 9 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 9 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) 0

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 NOV 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	09 NOV 2020 14:30
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3762161

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 NOV 2020

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

US3762161

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 NOV 2020

US3762161

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

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

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

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

Folder OID	UNBLND_DECIDE
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US3762161

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

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

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3762161

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00-23:59)	09:40 (24 HR)
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Collection date and time (derived)	19 JAN 2021 09:40
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US3762161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	09:42
Collection Date and Time (derived)	19 JAN 2021 09:42

US3762161

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Mar 2021 17:30:37

Generated On: 10 Jun 2021 09:43:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30
	1000001
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)	10 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)	20 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 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

PATIENT DOES HAVE
UNDERLYING CONDITIONS
SUCH AS DIABETES, HIGH
CHOLESTEROL,
HYPERTENSION, AND CABG.

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE KIDNEY INJURY
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)	10 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)	11 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 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

CREATININE:

11/10/20 17:59= 1.75

11/11/20 06:41= 1.32

11/12/07:02= 1.41

11/13/20 06:15= 1.53

11/14/20 08:01= 1.41

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	DIARRHEA
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)	9 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)	15 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 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	LEFT UPPER LOBE 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 type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 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)	18 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 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)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

CT CHEST SCAN WITHOUT
CONTRAST WAS PERFORMED

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

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE HYPONATREMIA
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)	10 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)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	HYPOKALEMIA
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)	10 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)	15 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.
FOR HYPOKALEMIA NO
MEDICATION WAS
ADMINISTERED.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000001
Adverse event	[DIARRHEA WITH] DEHYDRATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 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)	15 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 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)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	15 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

AEID	USA-US130-2020-MRNA-1273-P30 1000004
Adverse event	URINARY TRACT INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	24 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	24 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	25 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

PATIENT HAS BEEN
EXPERIENCING KIDNEY
STONES AND HAS GONE
THROUGH TO GET A STENT
ETC. PATIENT HAS
COMPLAINED OF PAIN WITH
URINATION AND WENT TO THE
EMERGENCY ROOM. ALL
CULTURES WERE NEGATIVE.
AND PATIENT WAS STARTED
ON ANTIBIOTIC. URINALYSIS
ABNORMAL, PRESENTING
WITH MODERATE BACTERIA,
LARGE AMOUNT OF BLOOD.
URINE PROTEIN 100MG/DL,
YEAST PRESENT AS WELL.

PT REPORTS MOST RECENT
EPISODE OF KIDNEY STONES IN
2013.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

AEID

Adverse event

BLACK STOOL

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)

10 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)

11 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

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

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

74 Y/O MALE WHO RECEIVED
SECOND DOSE OF PRODUCT ON
9/30 WITHOUT INCIDENT AND
WAS SEEN FOR ROUTINE F/U
ON 11/03 AND REPORTED NO
SYMPTOMS WHO WAS
ADMITTED TO WFBMC ON 11/10
WITH DIAGNOSIS OF
GASTROENTERITIS WITH
ASSOCIATED SEPSIS, ACUTE
KIDNEY INJURY, AND
POSSIBLE GI BLEED. HE HAD
REPORTED FEELING TIRED
WITH HEADACHES AND
MUSCLE ACHES ON 11/09 AND
WAS SEEN FOR A SICK VISIT. A
PCR FOR COVID-19 WAS
PERFORMED AT THE TIME WAS
NEGATIVE. ON TELEPHONE F/U
ON 11/10, HE REPORTED
INCREASED FATIGUE AND
DEVELOPMENT OF DIARRHEA
WITH BLACK STOOL. WE
RECOMMENDED GOING TO
EDC (WHICH HAD ALSO BEEN
RECOMMENDED BY PCP). HE
WAS ADMITTED FROM THE ED
AND DIAGNOSED AS ABOVE.

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

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

AEID	
Adverse event	FATIGUE
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)	9 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)	11 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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

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

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

AEID	
Adverse event	MINOR COUGH
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)	9 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)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

AEID	
Adverse event	HEADACHE
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)	5 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)	10 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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

AEID	
Adverse event	BODY ACHE
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)	9 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)	10 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	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

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

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

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

Yes ☒

No ☐

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

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 AUG 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 18:34:22

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Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

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 (2)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 FEB 2007	
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) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 FEB 2007	
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) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication POLYNEUROPATHY IN FEET

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 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)	4	
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 (5)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 (6)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

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 (6)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 1998
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)	4	
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) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication LEVEMIR

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 56

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

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
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) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 2007	
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 (8)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication OMNICEF
[CEFDINIR]

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA AND SEPSIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)	15 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)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication DOXYCYCLINE HYCLATE

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA AND SEPSIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)	15 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)	18 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication DEHYDRATION,
HYPONATREMIA, AND ACUTE
KIDNEY INJURY

Dose per administration 100

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

If dose unit is Other, specify ML/HR

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 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)		11 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 (11)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

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 (11)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 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) 10 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 (12)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)		10 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)		10 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"/>

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PNEUMONIA

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	15 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"/>	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication GENTAMICIN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 270

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

If dose unit is Other, specify

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

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)		15 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)		15 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"/>

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication AZO

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 97.5

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 (17)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 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)		20 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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)		15 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)		20 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 (19)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication CEFDINIR

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 300

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 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)	31 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 (20)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NEUROPATHY

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 18:34:22

Generated On: 10 Jun 2021 09:43:36

	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 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 18:34:23

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 DEC 2020	ULTRASOUND OF URINARY/RENAL SYSTEM	Adverse Event	
15 DEC 2020	RIGHT URETERAL STENT	Medical History	
28 DEC 2020	RIGHT URETERAL STENT REMOVAL	Medical History	
15 DEC 2020	KIDNEY STONE REMOVAL	Medical History	
10 NOV 2020	CT CHEST SCAN WITHOUT CONTRAST	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:43:36

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:43:36

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 ☐

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

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Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	12/NOV/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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:49
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	18/NOV/2020 15:00
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:36
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	20/NOV/2020 10:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	25/NOV/2020 21:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	26/JAN/2021 10:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	27/JAN/2021 17:39
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/MAR/2021 12:09
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/MAR/2021 13:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	11/MAR/2021 14:02
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	27/JAN/2021 17:38
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

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 18:34:24

Generated On: 10 Jun 2021 09:43:36

SAEID	USA-US130-2020-MRNA-1273-P301000004
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	JOHN
Investigator's Last Name	SANDERS
Site Address: Street	100 MEDICAL CENTER BLVD
Site Address: City	WINSTON-SALEM
Site Address: State	NC
Site Address: Postal Code	27157
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/MAR/2021 12:06
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

Audit

US3762161 (Prod: Wake Forest University Health Sciences)

US3762161

Form: Participant Creation

Generated On: 10 Jun 2021 09:43:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'US3762161'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:29:42

US3762161

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:07

US3762161

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:29:43

US3762161

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[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 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Clinic (Clinic)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:07

US3762161

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'SCRN'	System	02 Sep 2020 19:21:07

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered (b) (6) 1946'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:29:44

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Per CDM: Please complete the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 10:34:37
Query 'Per CDM: Please complete the form' answered with 'Done' (Site from DM).	Samantha Wheeler (b) (4)	21 Sep 2020 01:09:42
User entered '74'	(b) (4) Kaitlyn Van Leuvan	09 Sep 2020 20:26:03
User opened query 'Per CDM: Please complete the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 07:29:37

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'YEARS'	System	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '74'	System	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Male (M)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'I'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:43:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) Kaitlyn Van Leuvan (b) (4)	09 Sep 2020 20:26:03

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Sep 2020'	System	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2020'	System	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Amendment 3 (3)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:26

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 18:29:43

US3762161

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:43:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'I'	System	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:43:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:50:06

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:55:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:10
Data point term sent to Coder	System	28 Oct 2020 18:57:27
User entered 'Cataracts - Bilateral'	(b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2016'	System	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2016'	System	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2017'	System	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2017'	System	28 Oct 2020 18:56:43

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:10
Data point term sent to Coder	System	28 Oct 2020 18:57:27
User entered 'Diabetes'	(b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 1998'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 1998'	System	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '1998'	System	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:01

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:12
Data point term sent to Coder	System	28 Oct 2020 18:57:29
User entered 'High Cholesterol'	(b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2000'	System	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2000'	System	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:28

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness in feet - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:32
Data point term sent to Coder	System	28 Oct 2020 18:58:29
User entered 'Numbness in Feet'	(b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2010'	System	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2010'	System	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:57:57

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Tremor, LLT: Tremor - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:21
Data point term sent to Coder	System	28 Oct 2020 18:58:30
User entered 'Tremors'	(b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2011'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2011'	System	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2011'	System	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:58:17

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 20:24:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 20:24:21
User closed query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:12:58
Data point term sent to Coder	System	26 Jan 2021 20:29:40
Query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 20:29:06
Coding entries removed.	(b) (4), (b) (6)	26 Jan 2021 20:29:00
User entered 'DIABETIC NEUROPATHY in Feet and lower legs' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:29:00
User opened query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 12:21:16
Data hard unlocked.	(b) (4), (b) (6)	15 Jan 2021 12:21:12
Data hard locked.	(b) (4), (b) (6)	15 Jan 2021 12:21:09

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:35
Data point term sent to Coder	System	28 Oct 2020 18:59:30
User entered 'Diabetic Neuropathy'	(b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 1998'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 1998'	System	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '1998'	System	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	28 Oct 2020 18:58:44

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:37:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 13:37:31
Data point term sent to Coder	System	28 Oct 2020 18:59:31
User entered 'Stroke - Cerebellum'	(b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2006'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2006'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2006'	System	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2006'	System	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2006'	System	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2006'	System	28 Oct 2020 18:59:22

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:36
Data point term sent to Coder	System	28 Oct 2020 19:00:31
User entered 'Heart Attack'	(b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2007'	System	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2007'	System	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2007'	System	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2007'	System	28 Oct 2020 19:00:05

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:38
Data point term sent to Coder	System	28 Oct 2020 19:01:32
User entered 'Kidney Stones'	(b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
Signature has been broken.	(b) (4)	
	Samantha Wheeler (b) (4)	22 Feb 2021 19:51:48
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:51:48
	(b) (4)	
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
Signature has been broken.	(b) (4)	
	Samantha Wheeler (b) (4)	22 Feb 2021 19:51:48
	(b) (4)	
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:51:48
	(b) (4)	
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
	(b) (4)	
User entered 'UN UNK 2017'	(b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 1995'	System	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '1995'	System	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	22 Feb 2021 19:51:48
User entered 'Jan 2017'	System	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	22 Feb 2021 19:51:48
User entered '2017'	System	28 Oct 2020 19:00:42

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
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.	Coder Import (b) (4)	29 Oct 2020 19:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 19:55:40
Data point term sent to Coder	System	28 Oct 2020 19:02:36
User entered 'Vasectomy'	(b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 1981'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'UN UNK 1981'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 1981'	System	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '1981'	System	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 1981'	System	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '1981'	System	28 Oct 2020 19:02:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as SOC: Surgical and medical procedures, HLT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 08:59:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Mar 2021 08:59:40
Data point term sent to Coder	System	10 Mar 2021 18:01:15
User entered 'Cardiovascular arterial bypass graph'	(b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'UN UNK 2007'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2007'	System	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2007'	System	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Jan 2007'	System	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2007'	System	10 Mar 2021 18:01:14

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:08:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 18:08:56
Data point term sent to Coder	System	10 Mar 2021 18:07:54
User entered 'Hypertension'	(b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'UN Aug 2000'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'Aug 2000'	System	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2000'	System	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered empty.	System	10 Mar 2021 18:06:56

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '14:22'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '2 Sep 2020 14:22'	System	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '68' in	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42
DataPoint set to visible.	System	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '205' lb	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42
DataPoint set to visible.	System	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered '31.23532'	System	28 Oct 2020 18:48:42
DataPoint set to visible.	System	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'kg/m2'	System	28 Oct 2020 18:48:42
DataPoint set to visible.	System	02 Sep 2020 19:21:55

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'bpm'	System	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'breaths/min'	System	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'mmHg'	System	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User entered 'mmHg'	System	28 Oct 2020 18:48:42

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43

US3762161

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43

US3762161

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:10

US3762161

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:10

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 18:49:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 18:49:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 18:49:55
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Oct 2020 18:49:49
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:22:43
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:49:49

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:29:14

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 10:33:38
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:07:42
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated edc' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 20:32:49
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated edc' (Site from DM).	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 20:32:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:53:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2SEP2020 is reported under Visit 1 Day 1visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:17:30
User entered '02 Sep 2020'	Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:29:14

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4)	02 Sep 2020 19:29:14

US3762161

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'VISIT1'	System	02 Sep 2020 19:29:14

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:05:16

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '189561'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:05:16

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Sep 2020 19:05:16

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 11:10:58
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'Updated' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 00:52:22
User entered 'No (N)'	Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 00:52:13
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:03:18

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	21 Sep 2020 00:52:13

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 00:52:13

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 00:52:13

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	21 Sep 2020 00:52:13

US3762161

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	21 Sep 2020 00:52:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 04:57:49
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:57:49

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Pre-Dose (PREDOSE)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '14:22'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '02 Sep 2020 14:22'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '97.0' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '77'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'bpm'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '16'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'breaths/min'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '135'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '79'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered missing code ND - Not Done.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Post-Dose (POSTDOSE)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:50'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '02 Sep 2020 15:50'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '97.4' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '71'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'bpm'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '17'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'breaths/min'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '138'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '76'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 17:50:25

US3762161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:37

US3762161

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:50:37

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	Samantha Wheeler (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	Samantha Wheeler (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Samantha Wheeler (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:12'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '02 Sep 2020 15:12'	System	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Left Arm (LEFT ARM)'	Samantha Wheeler (b) (4)	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'ONCE'	System	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 19:29:34

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:01

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:01

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '14:59'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:01

US3762161

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '02 Sep 2020 14:59'	System	03 Nov 2020 17:51:01

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '02 Sep 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '14:55'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '02 Sep 2020 14:55'	System	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered empty.	System	03 Nov 2020 17:51:15

US3762161

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:23:01

US3762161

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Sep 2020 20:23:01

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' User entered 'Yes (Y)'	System	02 Sep 2020 19:55:55
	System	02 Sep 2020 19:55:55

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' User entered '97.4'	System	02 Sep 2020 19:55:55
	System	02 Sep 2020 19:55:55

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' User entered 'No (N)'	System	02 Sep 2020 19:55:55
	System	02 Sep 2020 19:55:55

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:55:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f8c94309-2985-4e42-9e51-4456587c61eb' User entered '02 Sep 2020 15:55'	System	02 Sep 2020 19:55:55
	System	02 Sep 2020 19:55:55

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 15:32'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:02'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:57'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 2'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:31:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' User entered 'Yes (Y)'	System	11 Sep 2020 02:20:59
	System	11 Sep 2020 02:20:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' User entered '97.7'	System	11 Sep 2020 02:20:59
	System	11 Sep 2020 02:20:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0'	System	11 Sep 2020 02:20:59
User entered 'No (N)'	System	11 Sep 2020 02:20:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bab6a60e-59c6-43f1-a2d5-fb1d0facb2b0' User entered '03 Sep 2020 14:32'	System	11 Sep 2020 02:20:59
	System	11 Sep 2020 02:20:59

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 3'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:07:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' User entered 'Yes (Y)'	System	11 Sep 2020 02:21:05
	System	11 Sep 2020 02:21:05

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' User entered '97.2'	System	11 Sep 2020 02:21:05
	System	11 Sep 2020 02:21:05

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' User entered 'No (N)'	System	11 Sep 2020 02:21:05
	System	11 Sep 2020 02:21:05

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '8a5f190c-5f79-4caf-ac7a-3bf4373837a7' User entered '04 Sep 2020 21:08'	System	11 Sep 2020 02:21:05
	System	11 Sep 2020 02:21:05

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 4'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:57:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' User entered 'Yes (Y)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:57:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' User entered '96.1'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69'	System	11 Sep 2020 02:21:06
User entered 'No (N)'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '83f2051d-2f66-4675-8218-5eba0b47ba69' User entered '05 Sep 2020 21:58'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 5'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' User entered 'Yes (Y)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' User entered '96.7'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78'	System	11 Sep 2020 02:21:08
User entered 'No (N)'	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54de4760-c8d1-4567-bc74-864e1fc4ca78' User entered '06 Sep 2020 22:53'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 6'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:39:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' User entered 'Yes (Y)'	System	11 Sep 2020 02:21:12
	System	11 Sep 2020 02:21:12

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:39:56', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' User entered '96.3'	System	11 Sep 2020 02:21:12
	System	11 Sep 2020 02:21:12

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728'	System	11 Sep 2020 02:21:12
User entered 'No (N)'	System	11 Sep 2020 02:21:12

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '72a89106-807f-478d-b382-aede6c19f728' User entered '07 Sep 2020 21:40'	System	11 Sep 2020 02:21:12
	System	11 Sep 2020 02:21:12

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 7'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:46:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' User entered 'Yes (Y)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' User entered '95.1'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' User entered 'No (N)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bbea2c1-dfdb-4d27-aa72-6d9e85d1685d' User entered '08 Sep 2020 22:47'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:08', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38'	System	02 Sep 2020 19:56:40
User entered 'None (1)'	System	02 Sep 2020 19:56:40

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' User entered 'No (N)'	System	02 Sep 2020 19:56:40
	System	02 Sep 2020 19:56:40

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' User entered 'No (N)'	System	02 Sep 2020 19:56:40
	System	02 Sep 2020 19:56:40

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38'	System	02 Sep 2020 19:56:40
User entered 'None (1)'	System	02 Sep 2020 19:56:40

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:56:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '222d59c1-4bf6-4386-a02d-4e5d20438f38' User entered '02 Sep 2020 15:56'	System	02 Sep 2020 19:56:40
	System	02 Sep 2020 19:56:40

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 15:32'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:02'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:57'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 2'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583'	System	11 Sep 2020 02:21:00
User entered 'None (1)'	System	11 Sep 2020 02:21:00

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' User entered 'No (N)'	System	11 Sep 2020 02:21:00
	System	11 Sep 2020 02:21:00

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' User entered 'No (N)'	System	11 Sep 2020 02:21:00
	System	11 Sep 2020 02:21:00

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:32:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583'	System	11 Sep 2020 02:21:00
User entered 'None (1)'	System	11 Sep 2020 02:21:00

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '9d08d977-c8f8-4836-b1aa-3a896d6a1583' User entered '03 Sep 2020 14:33'	System	11 Sep 2020 02:21:00
	System	11 Sep 2020 02:21:00

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 3'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5'	System	11 Sep 2020 02:21:06
User entered 'None (1)'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5'	System	11 Sep 2020 02:21:06
User entered 'No (N)'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:39', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5'	System	11 Sep 2020 02:21:06
User entered 'No (N)'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5'	System	11 Sep 2020 02:21:06
User entered 'None (1)'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '138b3fcc-2581-4f87-b2ed-805dc2aeb3f5'	System	11 Sep 2020 02:21:06
User entered '04 Sep 2020 21:08'	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 4'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58'	System	11 Sep 2020 02:21:07
User entered 'None (1)'	System	11 Sep 2020 02:21:07

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' User entered 'No (N)'	System	11 Sep 2020 02:21:07
	System	11 Sep 2020 02:21:07

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' User entered 'No (N)'	System	11 Sep 2020 02:21:07
	System	11 Sep 2020 02:21:07

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' User entered 'None (1)'	System	11 Sep 2020 02:21:07
	System	11 Sep 2020 02:21:07

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2b06f3b0-2db8-4bab-a904-aaf779016f58' User entered '05 Sep 2020 21:58'	System	11 Sep 2020 02:21:07
	System	11 Sep 2020 02:21:07

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 5'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac'	System	11 Sep 2020 02:21:08
User entered 'None (1)'	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac'	System	11 Sep 2020 02:21:08
User entered 'No (N)'	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:53:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac'	System	11 Sep 2020 02:21:08
User entered 'No (N)'	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac'	System	11 Sep 2020 02:21:08
User entered 'None (1)'	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a49a7dac-830c-41ee-bf4e-7eaf7dc9c8ac' User entered '06 Sep 2020 22:54'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 6'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c'	System	11 Sep 2020 02:21:13
User entered 'None (1)'	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' User entered 'No (N)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' User entered 'No (N)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c'	System	11 Sep 2020 02:21:13
User entered 'None (1)'	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2284a38d-f331-4c76-88b2-48c16bd9c03c' User entered '07 Sep 2020 21:40'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 7'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' User entered 'None (1)'	System	11 Sep 2020 02:21:14
	System	11 Sep 2020 02:21:14

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' User entered 'No (N)'	System	11 Sep 2020 02:21:14
	System	11 Sep 2020 02:21:14

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' User entered 'No (N)'	System	11 Sep 2020 02:21:14
	System	11 Sep 2020 02:21:14

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc'	System	11 Sep 2020 02:21:14
User entered 'None (1)'	System	11 Sep 2020 02:21:14

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a59d6c61-e19e-41e4-bd14-7cd9716b60bc' User entered '08 Sep 2020 22:47'	System	11 Sep 2020 02:21:14
	System	11 Sep 2020 02:21:14

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:57:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:57:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:13', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'None (0)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:19', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered 'No (N)'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-02T15:58:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '99dcdb88-d24b-46e6-a28b-501ee28b95a2' User entered '02 Sep 2020 15:58'	System	02 Sep 2020 19:58:24
	System	02 Sep 2020 19:58:24

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 15:32'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:02'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Sep 2020 18:57'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 2'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:13', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'None (0)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered 'No (N)'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-03T14:33:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '607c4e5f-8be2-409b-a009-1288e4675c2d' User entered '03 Sep 2020 14:33'	System	11 Sep 2020 02:21:04
	System	11 Sep 2020 02:21:04

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 3'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:08:56', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:08', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'None (0)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered 'No (N)'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-04T21:09:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '87892a4e-a147-47e4-a69b-750419bffb30' User entered '04 Sep 2020 21:09'	System	11 Sep 2020 02:21:06
	System	11 Sep 2020 02:21:06

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 4'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:58:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'None (0)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:59:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered 'No (N)'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-05T21:59:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '02e34d48-493b-4415-a60c-4d7e9ceba5cb' User entered '05 Sep 2020 21:59'	System	11 Sep 2020 02:21:08
	System	11 Sep 2020 02:21:08

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 5'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:19', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'None (0)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:41', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered 'No (N)'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-06T22:54:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6b359e3a-7267-43e2-a1d1-ce8d2c15493c' User entered '06 Sep 2020 22:54'	System	11 Sep 2020 02:21:11
	System	11 Sep 2020 02:21:11

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 6'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:39', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:55', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'None (0)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:40:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered 'No (N)'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-07T21:41:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f5afb5d2-1979-4098-9b97-64ac3dc094bb' User entered '07 Sep 2020 21:41'	System	11 Sep 2020 02:21:13
	System	11 Sep 2020 02:21:13

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 7'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'None (0)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda' User entered 'No (N)'	System	11 Sep 2020 02:21:15
	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-08T22:47:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1756140-ce87-4d67-87d9-4013973d9eda'	System	11 Sep 2020 02:21:15
User entered '08 Sep 2020 22:47'	System	11 Sep 2020 02:21:15

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 19:29:34

US3762161

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:04

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 14:44:47
User entered '9 Sep 2020'	(b) (4), (b) (6)	30 Sep 2020 20:24:04

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:04

US3762161

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:04

US3762161

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:09

US3762161

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Sep 2020 20:24:09

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:27

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:27

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:27

US3762161

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:27

US3762161

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:43

US3762161

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Sep 2020 20:24:43

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:56

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:56

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:56

US3762161

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:24:56

US3762161

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:02

US3762161

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Sep 2020 20:25:02

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:19

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:19

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:19

US3762161

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'VISIT2'	System	30 Sep 2020 20:25:19

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Pre-Dose (PREDOSE)'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:13'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '30 Sep 2020 15:13'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '98.9' F	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Oral (Oral)'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '81'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'bpm'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'breaths/min'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '121'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '70'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Post-Dose (POSTDOSE)'	James Lovette (b) (4) (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '16:20'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '30 Sep 2020 16:20'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '98.2' F	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Oral (Oral)'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '76'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'bpm'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Oct 2020 20:23:21
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 20:23:21
User entered missing code ND - Not Done; reason for change Data Entry Error	James Lovette (b) (4)	01 Oct 2020 20:23:21
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	01 Oct 2020 20:22:49
User entered empty.	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'breaths/min'	System	01 Oct 2020 20:23:21
User entered empty.	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '113'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '64'	James Lovette (b) (4)	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	01 Oct 2020 20:22:49

US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	James Lovette (b) (4)	01 Oct 2020 20:23:38

US3762161

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	01 Oct 2020 20:23:54
User entered '30 Sep 2020' reason for change: Data Entry Error	James Lovette (b) (4)	01 Oct 2020 20:23:54
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System (b) (4)	01 Oct 2020 20:23:38
User entered '20 Sep 2020'	James Lovette (b) (4)	01 Oct 2020 20:23:38

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:30'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '30 Sep 2020 15:30'	System	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'ONCE'	System	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 20:25:41

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	James Lovette (b) (4)	01 Oct 2020 20:24:11

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	James Lovette (b) (4)	01 Oct 2020 20:24:11

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:16'	James Lovette (b) (4)	01 Oct 2020 20:24:11

US3762161

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '30 Sep 2020 15:16'	System	01 Oct 2020 20:24:11

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '30 Sep 2020'	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '15:26'	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '30 Sep 2020 15:26'	System	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	James Lovette (b) (4) (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	James Lovette (b) (4)	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered empty.	System	01 Oct 2020 20:24:44

US3762161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:25:47

US3762161

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Sep 2020 20:25:47

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:26:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142'	System	30 Sep 2020 20:27:16
User entered 'Yes (Y)'	System	30 Sep 2020 20:27:16

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' User entered '98.2'	System	30 Sep 2020 20:27:16
	System	30 Sep 2020 20:27:16

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142'	System	30 Sep 2020 20:27:16
User entered 'No (N)'	System	30 Sep 2020 20:27:16

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ee5f18f4-85a4-41df-8320-e0966f122142' User entered '30 Sep 2020 16:27'	System	30 Sep 2020 20:27:16
	System	30 Sep 2020 20:27:16

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 15:50'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' User entered 'Yes (Y)'	System	01 Oct 2020 03:04:54
	System	01 Oct 2020 03:04:54

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' User entered '96.2'	System	01 Oct 2020 03:04:54
	System	01 Oct 2020 03:04:54

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:48', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' User entered 'No (N)'	System	01 Oct 2020 03:04:54
	System	01 Oct 2020 03:04:54

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:52', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '37c698ce-aa35-41d2-aa06-cdc076b26c5a' User entered '30 Sep 2020 23:04'	System	01 Oct 2020 03:04:54
	System	01 Oct 2020 03:04:54

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 19:15'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 2'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered 'Yes (Y)'	System	02 Oct 2020 06:29:37
	System	02 Oct 2020 06:29:37

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered '96.5'	System	02 Oct 2020 06:29:37
	System	02 Oct 2020 06:29:37

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered 'No (N)'	System	02 Oct 2020 06:29:37
	System	02 Oct 2020 06:29:37

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bcb0731d-8b3c-4ab4-8264-f1b625a93aea' User entered '02 Oct 2020 02:29'	System	02 Oct 2020 06:29:37
	System	02 Oct 2020 06:29:37

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 3'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:53:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' User entered 'Yes (Y)'	System	03 Oct 2020 02:54:17
	System	03 Oct 2020 02:54:17

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' User entered '97.5'	System	03 Oct 2020 02:54:17
	System	03 Oct 2020 02:54:17

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5'	System	03 Oct 2020 02:54:17
User entered 'No (N)'	System	03 Oct 2020 02:54:17

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c7592f26-de2a-4544-b074-a29fed9c70a5' User entered '02 Oct 2020 22:54'	System	03 Oct 2020 02:54:17
	System	03 Oct 2020 02:54:17

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 4'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered 'Yes (Y)'	System	04 Oct 2020 03:07:22
	System	04 Oct 2020 03:07:22

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered '97.3'	System	04 Oct 2020 03:07:22
	System	04 Oct 2020 03:07:22

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered 'No (N)'	System	04 Oct 2020 03:07:22
	System	04 Oct 2020 03:07:22

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'cd6c06f6-3d1d-4482-a50b-fd4e6b434d2e' User entered '03 Oct 2020 23:07'	System	04 Oct 2020 03:07:22
	System	04 Oct 2020 03:07:22

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 5'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' User entered 'Yes (Y)'	System	05 Oct 2020 01:16:57
	System	05 Oct 2020 01:16:57

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' User entered '96.8'	System	05 Oct 2020 01:16:57
	System	05 Oct 2020 01:16:57

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' User entered 'No (N)'	System	05 Oct 2020 01:16:57
	System	05 Oct 2020 01:16:57

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '848096ca-d168-4c5f-b7c6-4638d8ecfe37' User entered '04 Oct 2020 21:16'	System	05 Oct 2020 01:16:57
	System	05 Oct 2020 01:16:57

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 6'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' User entered 'Yes (Y)'	System	06 Oct 2020 13:43:55
	System	06 Oct 2020 13:43:55

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:49', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' User entered '96.5'	System	06 Oct 2020 13:43:55
	System	06 Oct 2020 13:43:55

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' User entered 'No (N)'	System	06 Oct 2020 13:43:55
	System	06 Oct 2020 13:43:55

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:54', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '891beeb0-e28b-4ced-bd53-d3cd2440a443' User entered '06 Oct 2020 09:43'	System	06 Oct 2020 13:43:55
	System	06 Oct 2020 13:43:55

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 7'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' User entered 'Yes (Y)'	System	07 Oct 2020 01:30:41
	System	07 Oct 2020 01:30:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' User entered '96.5'	System	07 Oct 2020 01:30:41
	System	07 Oct 2020 01:30:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:33', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' User entered 'No (N)'	System	07 Oct 2020 01:30:41
	System	07 Oct 2020 01:30:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f6c5f442-5f71-43a6-a3f7-b894e3163971' User entered '06 Oct 2020 21:30'	System	07 Oct 2020 01:30:41
	System	07 Oct 2020 01:30:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41'	System	30 Sep 2020 20:27:53
User entered 'None (1)'	System	30 Sep 2020 20:27:53

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' User entered 'No (N)'	System	30 Sep 2020 20:27:53
	System	30 Sep 2020 20:27:53

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' User entered 'No (N)'	System	30 Sep 2020 20:27:53
	System	30 Sep 2020 20:27:53

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' User entered 'None (1)'	System	30 Sep 2020 20:27:53
	System	30 Sep 2020 20:27:53

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:27:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'bc0987fd-1dfb-4a93-95dd-58a88b4d1e41' User entered '30 Sep 2020 16:27'	System	30 Sep 2020 20:27:53
	System	30 Sep 2020 20:27:53

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 15:50'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:04:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07'	System	01 Oct 2020 03:05:16
User entered 'None (1)'	System	01 Oct 2020 03:05:16

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07'	System	01 Oct 2020 03:05:16
User entered 'No (N)'	System	01 Oct 2020 03:05:16

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07'	System	01 Oct 2020 03:05:16
User entered 'No (N)'	System	01 Oct 2020 03:05:16

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07'	System	01 Oct 2020 03:05:16
User entered 'None (1)'	System	01 Oct 2020 03:05:16

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c15bce23-8e2a-452f-8f02-467e296b0d07'	System	01 Oct 2020 03:05:16
User entered '30 Sep 2020 23:05'	System	01 Oct 2020 03:05:16

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 19:15'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 2'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:29:55', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' User entered 'None (1)'	System	02 Oct 2020 06:30:15
	System	02 Oct 2020 06:30:15

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' User entered 'No (N)'	System	02 Oct 2020 06:30:15
	System	02 Oct 2020 06:30:15

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' User entered 'No (N)'	System	02 Oct 2020 06:30:15
	System	02 Oct 2020 06:30:15

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' User entered 'None (1)'	System	02 Oct 2020 06:30:15
	System	02 Oct 2020 06:30:15

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c1ac1eab-94fd-41dc-94b2-f19b0bce6228' User entered '02 Oct 2020 02:30'	System	02 Oct 2020 06:30:15
	System	02 Oct 2020 06:30:15

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 3'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'None (1)'	System	03 Oct 2020 02:59:09
	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:54:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'Yes (Y)'	System	03 Oct 2020 02:59:09
	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered '7'	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'Yes (Y)'	System	03 Oct 2020 02:59:09
	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:58:54', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered '3'	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered 'None (1)'	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '51643f69-c818-4b7c-bc05-3b84e775094a' User entered '02 Oct 2020 22:59'	System	03 Oct 2020 02:59:09
	System	03 Oct 2020 02:59:09

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 4'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa'	System	04 Oct 2020 03:08:06
User entered 'None (1)'	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' User entered 'No (N)'	System	04 Oct 2020 03:08:06
	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa'	System	04 Oct 2020 03:08:06
User entered 'Yes (Y)'	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:07:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' User entered '3'	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa'	System	04 Oct 2020 03:08:06
User entered 'None (1)'	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:04', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5cc01959-ab0c-4d93-b178-1d67375c9aaa' User entered '03 Oct 2020 23:08'	System	04 Oct 2020 03:08:06
	System	04 Oct 2020 03:08:06

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 5'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:16:58', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' User entered 'None (1)'	System	05 Oct 2020 01:17:14
	System	05 Oct 2020 01:17:14

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' User entered 'No (N)'	System	05 Oct 2020 01:17:14
	System	05 Oct 2020 01:17:14

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' User entered 'No (N)'	System	05 Oct 2020 01:17:14
	System	05 Oct 2020 01:17:14

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' User entered 'None (1)'	System	05 Oct 2020 01:17:14
	System	05 Oct 2020 01:17:14

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'c5d36cd0-48c0-43df-bf1c-bcaf2044fa61' User entered '04 Oct 2020 21:17'	System	05 Oct 2020 01:17:14
	System	05 Oct 2020 01:17:14

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 6'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:43:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' User entered 'None (1)'	System	06 Oct 2020 13:44:18
	System	06 Oct 2020 13:44:18

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:03', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' User entered 'No (N)'	System	06 Oct 2020 13:44:18
	System	06 Oct 2020 13:44:18

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' User entered 'No (N)'	System	06 Oct 2020 13:44:18
	System	06 Oct 2020 13:44:18

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:11', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' User entered 'None (1)'	System	06 Oct 2020 13:44:18
	System	06 Oct 2020 13:44:18

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '81459ae7-a4ae-47ed-8522-e54f6c83bff0' User entered '06 Oct 2020 09:44'	System	06 Oct 2020 13:44:18
	System	06 Oct 2020 13:44:18

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 7'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:41', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' User entered 'None (1)'	System	07 Oct 2020 01:30:57
	System	07 Oct 2020 01:30:57

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' User entered 'No (N)'	System	07 Oct 2020 01:30:57
	System	07 Oct 2020 01:30:57

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:47', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' User entered 'No (N)'	System	07 Oct 2020 01:30:57
	System	07 Oct 2020 01:30:57

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' User entered 'None (1)'	System	07 Oct 2020 01:30:57
	System	07 Oct 2020 01:30:57

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:53', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '33bb6b24-dfc1-4fc1-9e63-1f6afe800813' User entered '06 Oct 2020 21:30'	System	07 Oct 2020 01:30:57
	System	07 Oct 2020 01:30:57

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'None (0)'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aee1b' User entered 'No (N)'	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T16:28:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5a9e9049-add3-46c9-a954-f5ef41aeeclb' User entered '30 Sep 2020 16:28'	System	30 Sep 2020 20:28:42
	System	30 Sep 2020 20:28:42

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 15:50'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 18:20'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered 'None (0)'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2'	System	01 Oct 2020 03:05:40
User entered 'No (N)'	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-09-30T23:05:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1cee65bd-7466-4653-832d-45b3db71a3e2' User entered '30 Sep 2020 23:05'	System	01 Oct 2020 03:05:40
	System	01 Oct 2020 03:05:40

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '30 Sep 2020 19:15'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 2'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:27', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:30:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered 'None (0)'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:31:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727'	System	02 Oct 2020 06:31:09
User entered 'No (N)'	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T02:31:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'b1842b1a-89af-46ff-b412-cd01063cb727' User entered '02 Oct 2020 02:31'	System	02 Oct 2020 06:31:09
	System	02 Oct 2020 06:31:09

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 3'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'None (0)'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered 'No (N)'	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-02T22:59:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '668a5470-4576-4ce0-af70-47495ee6561f' User entered '02 Oct 2020 22:59'	System	03 Oct 2020 02:59:37
	System	03 Oct 2020 02:59:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 4'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:15', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:21', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:24', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'None (0)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered 'No (N)'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-03T23:08:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7e7a9bfc-9782-4dd8-8f1c-87b827a31b2e' User entered '03 Oct 2020 23:08'	System	04 Oct 2020 03:08:37
	System	04 Oct 2020 03:08:37

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 5'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:20', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:23', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:28', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'None (0)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered 'No (N)'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-04T21:17:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '54ca638b-b66a-4396-bd12-47c36bf95c8e' User entered '04 Oct 2020 21:17'	System	05 Oct 2020 01:17:38
	System	05 Oct 2020 01:17:38

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 6'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:22', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:25', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:29', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:35', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'None (0)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:44', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered 'No (N)'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T09:44:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '26aa56fd-1d85-4c51-adc8-63e550a2621b' User entered '06 Oct 2020 09:44'	System	06 Oct 2020 13:44:52
	System	06 Oct 2020 13:44:52

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	30 Sep 2020 20:25:41
User entered 'Day 7'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:30:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:02', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:07', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:10', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered 'None (0)'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53'	System	07 Oct 2020 01:31:18
User entered 'No (N)'	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-10-06T21:31:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '903cfe7f-1cd6-4931-9111-23c647d5df53' User entered '06 Oct 2020 21:31'	System	07 Oct 2020 01:31:18
	System	07 Oct 2020 01:31:18

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 20:25:41

US3762161

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:43:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 20:25:41

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:15

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '07 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:15

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:15

US3762161

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:15

US3762161

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:21

US3762161

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	21 Oct 2020 15:26:21

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:35

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '14 Oct 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:35

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:35

US3762161

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:35

US3762161

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:41

US3762161

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	21 Oct 2020 15:26:41

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:54

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	21 Oct 2020 15:27:23
User entered '21 Oct 2020' reason for change: Data Entry Error	System	21 Oct 2020 15:27:23
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:27:23
User entered '20 Oct 2020'	System	21 Oct 2020 15:26:54
	Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:54

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:54

US3762161

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:26:54

US3762161

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	21 Oct 2020 15:27:29

US3762161

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	21 Oct 2020 15:27:29

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 15:38:52

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '03 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 15:38:52

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Clinic (Clinic)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 15:38:52

US3762161

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'VISIT3'	System	03 Nov 2020 15:38:52

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '03 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '09:41'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '03 Nov 2020 09:41'	System	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '97.7' F	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Oral (Oral)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '65'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'bpm'	System	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '16'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'breaths/min'	System	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '127'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '67'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'mmHg'	System	03 Nov 2020 16:31:37

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55

US3762161

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:48

US3762161

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:31:48

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:32:05

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '03 Nov 2020'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:32:05

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered '10:03'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:32:05

US3762161

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered '03 Nov 2020 10:03'	System	03 Nov 2020 16:32:05

US3762161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	12 Feb 2021 23:06:12
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 16:32:10

US3762161

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	03 Nov 2020 16:32:10

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 64'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' User entered 'No (N)'	System	03 Nov 2020 03:42:28
	System	03 Nov 2020 03:42:28

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:16', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' User entered 'No (N)'	System	03 Nov 2020 03:42:28
	System	03 Nov 2020 03:42:28

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-02T22:42:24', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'f0a02ba5-e26d-4b63-b3a6-c6a74ea0ac3d' User entered '02 Nov 2020 22:42:24'	System	03 Nov 2020 03:42:28
	System	03 Nov 2020 03:42:28

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:31:58
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 71'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Have you been exposed to someone with 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered 'Day 78'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Have you been exposed to someone with 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 19:29:34

US3762161

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:46:55
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 02:50:20
Data entry locked.	System	02 Sep 2020 19:29:34
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 19:29:34

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:23:37', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered 'Yes (Y)'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:23:43', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered 'No (N)'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:23:48', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered 'No (N)'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:23:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered 'Yes (Y)'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Please 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:24:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-11-30T11:24:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e0db9080-3300-4d0b-82ba-3ddb8e2386b3'	System	30 Nov 2020 16:24:25
User entered '30 Nov 2020 11:24:14'	System	30 Nov 2020 16:24:25

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-12T00:18:09', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '29262496-d9d8-4207-89ce-bd6490ece31a' User entered 'No (N)'	System	12 Dec 2020 05:18:23
	System	12 Dec 2020 05:18:23

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-12T00:18:13', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '29262496-d9d8-4207-89ce-bd6490ece31a'	System	12 Dec 2020 05:18:23
User entered 'No (N)'	System	12 Dec 2020 05:18:23

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-12T00:18:17', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '29262496-d9d8-4207-89ce-bd6490ece31a' User entered '12 Dec 2020 00:18:17'	System	12 Dec 2020 05:18:23
	System	12 Dec 2020 05:18:23

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:54:06', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f'	System	19 Dec 2020 23:54:41
User entered 'Yes (Y)'	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:53:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f' User entered 'No (N)'	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:53:56', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f' User entered 'No (N)'	System	19 Dec 2020 23:54:41
	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:54:14', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f'	System	19 Dec 2020 23:54:41
User entered 'Yes (Y)'	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:54:18', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f'	System	19 Dec 2020 23:54:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-19T18:54:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '835bb422-555c-4768-851b-06f6a3ec3a8f' User entered '19 Dec 2020 18:54:30'	System	19 Dec 2020 23:54:41
	System	19 Dec 2020 23:54:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T11:59:59', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a' User entered 'Yes (Y)'	System	25 Dec 2020 17:00:55
	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T12:00:05', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a' User entered 'No (N)'	System	25 Dec 2020 17:00:55
	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T12:00:12', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a' User entered 'No (N)'	System	25 Dec 2020 17:00:55
	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T12:00:24', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a' User entered 'Yes (Y)'	System	25 Dec 2020 17:00:55
	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T12:00:33', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a'	System	25 Dec 2020 17:00:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2020-12-25T12:00:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6ee224e6-d1cc-4670-ac58-9a122dd3287a' User entered '25 Dec 2020 12:00:42'	System	25 Dec 2020 17:00:55
	System	25 Dec 2020 17:00:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-01T21:34:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5f50d21f-42f4-44ca-af00-49859c637d84'	System	02 Jan 2021 02:41:55
User entered 'No (N)'	System	02 Jan 2021 02:41:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-01T21:34:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5f50d21f-42f4-44ca-af00-49859c637d84'	System	02 Jan 2021 02:41:55
User entered 'No (N)'	System	02 Jan 2021 02:41:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-01T21:34:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5f50d21f-42f4-44ca-af00-49859c637d84' User entered '01 Jan 2021 21:34:50'	System	02 Jan 2021 02:41:55
	System	02 Jan 2021 02:41:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-08T19:49:26', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e14bd804-766d-45a7-975e-203770872a4a'	System	09 Jan 2021 00:49:41
User entered 'No (N)'	System	09 Jan 2021 00:49:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-08T19:49:30', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e14bd804-766d-45a7-975e-203770872a4a'	System	09 Jan 2021 00:49:41
User entered 'No (N)'	System	09 Jan 2021 00:49:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-08T19:49:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e14bd804-766d-45a7-975e-203770872a4a'	System	09 Jan 2021 00:49:41
User entered '08 Jan 2021 19:49:38'	System	09 Jan 2021 00:49:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-16T00:05:51', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6e3e7da9-f97d-456a-8657-a1ca4069c0f4'	System	16 Jan 2021 05:06:55
User entered 'No (N)'	System	16 Jan 2021 05:06:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-16T00:05:57', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6e3e7da9-f97d-456a-8657-a1ca4069c0f4'	System	16 Jan 2021 05:06:55
User entered 'No (N)'	System	16 Jan 2021 05:06:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-16T00:06:01', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '6e3e7da9-f97d-456a-8657-a1ca4069c0f4' User entered '16 Jan 2021 00:06:01'	System	16 Jan 2021 05:06:55
	System	16 Jan 2021 05:06:55

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-23T02:34:34', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bc750a2-f61d-48df-b7aa-5ad658488b40' User entered 'No (N)'	System	23 Jan 2021 07:34:45
	System	23 Jan 2021 07:34:45

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-23T02:34:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bc750a2-f61d-48df-b7aa-5ad658488b40'	System	23 Jan 2021 07:34:45
User entered 'No (N)'	System	23 Jan 2021 07:34:45

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-23T02:34:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '5bc750a2-f61d-48df-b7aa-5ad658488b40' User entered '23 Jan 2021 02:34:42'	System	23 Jan 2021 07:34:45
	System	23 Jan 2021 07:34:45

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-29T21:26:46', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2cfac0b3-c0ce-41c1-802e-df964fd58f24' User entered 'No (N)'	System	30 Jan 2021 02:26:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-29T21:26:50', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2cfac0b3-c0ce-41c1-802e-df964fd58f24'	System	30 Jan 2021 02:26:59
User entered 'No (N)'	System	30 Jan 2021 02:26:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-01-29T21:26:54', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '2cfac0b3-c0ce-41c1-802e-df964fd58f24' User entered '29 Jan 2021 21:26:54'	System	30 Jan 2021 02:26:59

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-06T01:31:31', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b9ca51a-1573-4323-9631-b2e482e5eeb9' User entered 'No (N)'	System	06 Feb 2021 06:33:04
	System	06 Feb 2021 06:33:04

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-06T01:31:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b9ca51a-1573-4323-9631-b2e482e5eeb9' User entered 'No (N)'	System	06 Feb 2021 06:33:04

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-06T01:31:40', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b9ca51a-1573-4323-9631-b2e482e5eeb9' User entered '06 Feb 2021 01:31:40'	System	06 Feb 2021 06:33:04
	System	06 Feb 2021 06:33:04

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-13T12:06:32', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1e72980d-09cd-46cb-8856-2d9581938cfc' User entered 'No (N)'	System	13 Feb 2021 17:13:20
	System	13 Feb 2021 17:13:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-13T12:06:38', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1e72980d-09cd-46cb-8856-2d9581938cfc' User entered 'No (N)'	System	13 Feb 2021 17:13:20
	System	13 Feb 2021 17:13:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-13T12:06:42', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1e72980d-09cd-46cb-8856-2d9581938cfc' User entered '13 Feb 2021 12:06:42'	System	13 Feb 2021 17:13:20
	System	13 Feb 2021 17:13:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-19T17:10:36', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'eba40249-094f-440d-b101-f2b90a5b204f' User entered 'No (N)'	System	27 Feb 2021 05:37:22

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-19T17:10:41', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'eba40249-094f-440d-b101-f2b90a5b204f' User entered 'No (N)'	System	27 Feb 2021 05:37:22

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-19T17:10:45', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'eba40249-094f-440d-b101-f2b90a5b204f' User entered '19 Feb 2021 17:10:45'	System	27 Feb 2021 05:37:22

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-27T00:37:19-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '561a0a03-3c1e-407d-9881-79f55e275b0c' User entered 'No (N)'	System	27 Feb 2021 05:37:35
	System	27 Feb 2021 05:37:35

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-27T00:37:22-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '561a0a03-3c1e-407d-9881-79f55e275b0c' User entered 'No (N)'	System	27 Feb 2021 05:37:35

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-02-27T00:37:26-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '561a0a03-3c1e-407d-9881-79f55e275b0c' User entered '27 Feb 2021 05:37:26'	System	27 Feb 2021 05:37:35
	System	27 Feb 2021 05:37:35

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-05T00:04:13-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a2fc0b55-fbce-4de6-b7a0-03c1d6245536'	System	05 Mar 2021 05:05:56
User entered 'No (N)'	System	05 Mar 2021 05:05:56

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-05T00:04:17-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a2fc0b55-fbce-4de6-b7a0-03c1d6245536'	System	05 Mar 2021 05:05:56
User entered 'No (N)'	System	05 Mar 2021 05:05:56

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-05T00:04:20-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'a2fc0b55-fbce-4de6-b7a0-03c1d6245536'	System	05 Mar 2021 05:05:56
User entered '05 Mar 2021 00:04:20'	System	05 Mar 2021 05:05:56

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-12T13:11:49-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '80483916-eca6-4c86-8278-e231d3bdf929' User entered 'No (N)'	System	12 Mar 2021 18:12:00
	System	12 Mar 2021 18:12:00

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-12T13:11:52-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '80483916-eca6-4c86-8278-e231d3bdf929'	System	12 Mar 2021 18:12:00
User entered 'No (N)'	System	12 Mar 2021 18:12:00

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-12T13:11:55-05:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '80483916-eca6-4c86-8278-e231d3bdf929'	System	12 Mar 2021 18:12:00
User entered '12 Mar 2021 13:11:55'	System	12 Mar 2021 18:12:00

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-19T12:44:05-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b84557b-9f3c-4427-b86f-fd4fd185e6c2'	System	29 Apr 2021 21:15:41
User entered 'No (N)'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-19T12:44:09-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b84557b-9f3c-4427-b86f-fd4fd185e6c2'	System	29 Apr 2021 21:15:41
User entered 'No (N)'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-19T12:44:13-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '0b84557b-9f3c-4427-b86f-fd4fd185e6c2'	System	29 Apr 2021 21:15:41
User entered '19 Mar 2021 12:44:13'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-26T11:57:56-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e80cbc52-f927-4436-8746-47de3e6507b2'	System	29 Apr 2021 21:15:41
User entered 'No (N)'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-26T11:58:04-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e80cbc52-f927-4436-8746-47de3e6507b2'	System	29 Apr 2021 21:15:41
User entered 'No (N)'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-03-26T11:58:07-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'e80cbc52-f927-4436-8746-47de3e6507b2'	System	29 Apr 2021 21:15:41
User entered '26 Mar 2021 11:58:07'	System	29 Apr 2021 21:15:41

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-04T02:42:08-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '73a08479-f4d8-44d0-8a79-b3f27ecbbb41' User entered 'No (N)'	System	29 Apr 2021 21:15:42
	System	29 Apr 2021 21:15:42

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-04T02:42:16-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '73a08479-f4d8-44d0-8a79-b3f27ecbbb41' User entered 'No (N)'	System	29 Apr 2021 21:15:42

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-04T02:42:20-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '73a08479-f4d8-44d0-8a79-b3f27ecbbb41' User entered '04 Apr 2021 02:42:20'	System	29 Apr 2021 21:15:42
	System	29 Apr 2021 21:15:42

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:12-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae'	System	29 Apr 2021 21:15:51
User entered 'Yes (Y)'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:16-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae'	System	29 Apr 2021 21:15:51
User entered 'No (N)'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:21-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae' User entered 'No (N)'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:29-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae'	System	29 Apr 2021 21:15:51
User entered 'Yes (Y)'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Please 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:37-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae'	System	29 Apr 2021 21:15:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-09T18:51:41-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '7f359347-00fa-44ff-ad4e-44e422ce98ae'	System	29 Apr 2021 21:15:51
User entered '09 Apr 2021 18:51:41'	System	29 Apr 2021 21:15:51

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-16T12:50:44-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ab30a0f6-70b5-4d71-9eb9-b201b4298af4'	System	29 Apr 2021 21:15:44
User entered 'No (N)'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-16T12:50:47-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ab30a0f6-70b5-4d71-9eb9-b201b4298af4'	System	29 Apr 2021 21:15:44
User entered 'No (N)'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-16T12:50:50-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'ab30a0f6-70b5-4d71-9eb9-b201b4298af4' User entered '16 Apr 2021 12:50:50'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-23T16:02:53-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '810f2228-47fe-40d3-b859-48f512276b93'	System	29 Apr 2021 21:15:44
User entered 'No (N)'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-23T16:02:56-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '810f2228-47fe-40d3-b859-48f512276b93'	System	29 Apr 2021 21:15:44
User entered 'No (N)'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-23T16:02:59-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '810f2228-47fe-40d3-b859-48f512276b93'	System	29 Apr 2021 21:15:44
User entered '23 Apr 2021 16:02:59'	System	29 Apr 2021 21:15:44

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-30T16:47:33-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'fa09f41d-7bbe-472c-b30a-a2e16d7de834'	System	30 Apr 2021 20:47:43
User entered 'No (N)'	System	30 Apr 2021 20:47:43

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

Have you been exposed to someone with 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 (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-30T16:47:36-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'fa09f41d-7bbe-472c-b30a-a2e16d7de834'	System	30 Apr 2021 20:47:43
User entered 'No (N)'	System	30 Apr 2021 20:47:43

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-30T16:47:40-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: 'fa09f41d-7bbe-472c-b30a-a2e16d7de834' User entered '30 Apr 2021 16:47:40'	System	30 Apr 2021 20:47:43
	System	30 Apr 2021 20:47:43

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:50:20

US3762161

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:50:20
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:50:20

US3762161

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:43:36

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)	02 May 2021 15:44:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-01T10:17:05-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1e803da0-36db-4cae-bb78-cbe1195737da' User entered 'No (N)'	System	29 Apr 2021 21:15:41
	System	29 Apr 2021 21:15:41

US3762161

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:43:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:44:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8359DE4C-9184-4AAF-A3DA-724FC7FD7A8C)', Time: '2021-04-01T10:17:09-04:00', User OID: 'PatientReportedOutcome (US3762161)', ODM File OID: '1e803da0-36db-4cae-bb78-cbe1195737da' User entered '01 Apr 2021 10:17:09'	System	29 Apr 2021 21:15:41
	System	29 Apr 2021 21:15:41

US3762161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:21

US3762161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 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)	04 Dec 2020 08:36:45
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'correct per source' (Site from System).	Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:34
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Nov 2020 18:03:21
User entered '30 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:21

US3762161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:21

US3762161

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
User entered empty.	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:21

US3762161

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User signature succeeded.	John Sanders (b) (4)	08 Mar 2021 18:32:20
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	30 Nov 2020 18:03:39

US3762161

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 16:29:55
User entered 'I'	System	30 Nov 2020 18:03:39

US3762161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:24

US3762161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:24

US3762161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:24

US3762161

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:24

US3762161

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 17:25:32

US3762161

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User entered 'I'	System	28 Dec 2020 17:25:32

US3762161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:30:23

US3762161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:30:23

US3762161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:30:23

US3762161

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:30:23

US3762161

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:30:32

US3762161

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User entered 'I'	System	26 Jan 2021 20:30:32

US3762161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 15:37:13

US3762161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '25 Feb 2021'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	25 Feb 2021 15:37:13

US3762161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 15:37:13

US3762161

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:43:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 15:37:13

US3762161

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Samantha Wheeler (b) (4)	25 Feb 2021 15:37:16

US3762161

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:24:52
User entered 'I'	System	25 Feb 2021 15:37:16

US3762161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:36

US3762161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:36

US3762161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:36

US3762161

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 13:14:36

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 13:14:44

US3762161

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:49

US3762161

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:14:49

US3762161

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:26

US3762161

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:26

US3762161

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '09:20'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:26

US3762161

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '1 Apr 2021 09:20'	System	01 Apr 2021 13:48:26

US3762161

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:48:32

US3762161

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:43:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 13:48:32

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:43:36

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:00
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:23
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:33:33

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:43:36

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:00
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:23
User entered '14:25'	(b) (4), (b) (6)	10 Nov 2020 21:33:33

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:43:36

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:00
User entered '9 Nov 2020 14:25'	System	10 Nov 2020 21:33:33

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:43:36

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:00
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:23
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	10 Nov 2020 21:33:33

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:43:36

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:00
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:33:33

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 21:35:32
User entered 'Day 1 (Day 1)'	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered '95'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User entered '%'	System	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered '98.4' F	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Severe (Severe)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'None (None)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:43:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:36
User entered 'Mild (Mild)'	(b) (4), (b) (6)	10 Nov 2020 21:35:06

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Day 1 (Day 1)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '05 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User entered '%'	System	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Severe (Severe)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:36:42
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:43:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:36:42

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Day 2 (Day 2)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '06 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User entered '%'	System	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Severe (Severe)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:37:52

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:43:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Mild (Mild)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:37:52
	(b) (4)	

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Day 3 (Day 3)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '07 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User entered '%'	System	19 Nov 2020 21:39:24

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Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Severe (Severe)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Severe (Severe)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:39:24
	(b) (4)	

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:39:24
	(b) (4)	

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:43:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:39:24

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Day 4 (Day 4)'	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '08 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User entered '%'	System	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:41:27
	(b) (4)	

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Severe (Severe)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'Moderate (Moderate)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:43:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:06
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:50:54
User entered 'None (None)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:41:27

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[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 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

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 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 21:35:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 21:35:41
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 21:35:35
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	19 Nov 2020 18:04:49
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[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 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered 'No (N)'	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	19 Nov 2020 18:04:49
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:04:49
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 21:35:35

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:43:36

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:11
User entered '0'	System	10 Nov 2020 21:35:41

US3762161

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:43:36

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:54:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:43:47
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:20:08

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4)	
	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4)	
	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:43:36

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:43:36

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33

US3762161

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:45:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4)	
	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:33
	(b) (4)	

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:51:13
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:51:13
User entered '09 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:52
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 21:51:13
User entered 'Clinic (Clinic)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:52
User entered 'SICKD1'	System	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '09 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '14:30'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User entered '09 Nov 2020 14:30'	System	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4)	19 Nov 2020 21:58:38
DataPoint set to visible.	(b) (4) System	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered missing code ND - Not Done.	Samantha Wheeler (b) (4)	19 Nov 2020 21:58:38
DataPoint set to visible.	(b) (4) System	19 Nov 2020 20:37:09

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '98.4' F	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered 'Oral (Oral)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '88'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User entered 'bpm'	System	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '16'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User entered 'breaths/min'	System	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '137'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User entered 'mmHg'	System	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 22:02:27
User entered '78'	Samantha Wheeler (b) (4)	19 Nov 2020 21:58:38
	(b) (4)	

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56
User entered 'mmHg'	System	19 Nov 2020 21:58:38

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56

US3762161

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:36

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:30:56

US3762161

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:31:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:48
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:58:59

US3762161

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:43:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:31:02
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 22:02:48
User entered '09 Nov 2020'	Samantha Wheeler (b) (4)	19 Nov 2020 21:58:59
	(b) (4)	

US3762161

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:43:36

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:31:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:59
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:59:25

US3762161

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:43:36

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:31:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 22:02:59
User entered '09 Nov 2020'	Samantha Wheeler (b) (4) (b) (4)	19 Nov 2020 21:59:25

US3762161

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

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:03

US3762161

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

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '19 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:03

US3762161

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

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[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 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Clinic (Clinic)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:03

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

Form: Visit Date

Generated On: 10 Jun 2021 09:43:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:58:03

US3762161

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '19 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[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 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:24:37

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:24:37

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '19 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

US3762161

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:51:49
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

US3762161

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:51:49
User entered 'mRNA-1273 (mRNA-1273)'	Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

US3762161

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'No (N)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:22

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User entered empty.	System	19 Jan 2021 21:58:22

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

Form: Unblinding

Generated On: 10 Jun 2021 09:43:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User entered empty.	System	19 Jan 2021 21:58:22

US3762161

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:38

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '19 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:38

US3762161

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '09:40'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:38

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User entered '19 Jan 2021 09:40'	System	19 Jan 2021 21:58:38

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:43:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:50

US3762161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:43:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '19 Jan 2021'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:50

US3762161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:43:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '09:42'	(b) (4) Kaitlyn Van Leuvan (b) (4)	19 Jan 2021 21:58:50

US3762161

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:24:26
User entered '19 Jan 2021 09:42'	System	19 Jan 2021 21:58:50

US3762161

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:43:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:20
User signature succeeded.	John Sanders (b) (4)	23 Mar 2021 17:30:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:34:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:15:19

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:35:43
User entered 'USA-US130-2020-mRNA-1273-P301000001'	System	12 Nov 2020 15:35:24
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 15:35:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
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)	17 Nov 2020 20:41:50
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 20:41:50
Data point term sent to Coder	System	17 Nov 2020 20:41:22
Coding entries removed.	Samantha Wheeler (b) (4) (b) (4)	17 Nov 2020 20:41:20
User entered 'Sepsis' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	17 Nov 2020 20:41:20
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Intestinal sepsis, LLT: Intestinal sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 11:43:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 11:43:41
Data point term sent to Coder	System	13 Nov 2020 19:51:43
User closed query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' (Site from System).	System	13 Nov 2020 19:51:05
Query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' answered with 'Condition split into separate records updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:51:05
User entered 'GASTROENTERITIS WITH SEPSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:50:42
Data point term sent to Coder	System	13 Nov 2020 19:44:33

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'GASTROENTERITIS WITH SEPSIS, AND POSSIBLE GI BLEED.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:44:07
User opened query 'CDM Coding, please add to the text a unifying diagnosis. Alternatively split into separate records, as 'GASTROENTERITIS', 'SEPSIS', 'ACUTE KIDNEY INJURY' and 'POSSIBLE GI BLEED', reporting each event with all relevant information e.g. start and stop dates etc' (Site from System).	Coder Import (b) (4)	12 Nov 2020 03:30:40
Data point term sent to Coder	System	11 Nov 2020 19:31:23
User entered 'Gastroenteritis with sepsis, acute Kidney injury and possible GI Bleed.'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '10 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	17 Nov 2020 20:41:20
User entered '09 Nov 2020'	Kaitlyn Van Leuvan	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
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 20:41:41
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	17 Nov 2020 20:41:41
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	17 Nov 2020 20:41:20
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).	(b) (4), (b) (6)	17 Nov 2020 05:45:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Nov 2020 19:40:25
User entered '00:00' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:40:25
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'Start time is unknown per source ' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:39:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Nov 2020 19:39:17
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	13 Nov 2020 19:39:17
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	11 Nov 2020 19:31:23
User entered '00:00'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 20:41:41
User entered '10 Nov 2020 00:00'	System	17 Nov 2020 20:41:20
User entered '09 Nov 2020 00:00'	System	13 Nov 2020 19:40:25
User entered '09 Nov 2020 UN:UN' (non-conformant).	System	13 Nov 2020 19:39:17
User entered '09 Nov 2020 00:00'	System	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:03:15
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'end date updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:39:04
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:16:26
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User closed query 'PV Query: Please provide the event end date for sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:30
Query 'PV Query: Please provide the event end date for sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' answered with 'i have provided all end dates for everything I am aware of.' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 19:21:24
User opened query 'PV Query: Please provide the event end date for sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:20
Query 'PV Query: Please provide the event end date ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:42:19
User opened query 'PV Query: Please provide the event end date ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:39:06
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '1'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Nov 2020 05:45:28
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 'Hospital admission updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:38:57
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	11 Nov 2020 19:31:23
User entered 'I'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '10 Nov 2020'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Hospital discharge date was reported as 15 Nov 2020 for events upper left lobe pneumonia, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add the hospital discharge date for events sepsis, acute kidney injury, and diarrhea in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:27
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
Query 'PV Query: Hospital discharge date was reported as 15 Nov 2020 for events upper left lobe pneumonia, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add the hospital discharge date for events sepsis, acute kidney injury, and diarrhea in the eCRF.' answered with 'updated' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 18:29:39
DataPoint Un-verified.	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 18:08:13
User opened query 'PV Query: Hospital discharge date was reported as 15 Nov 2020 for events upper left lobe pneumonia, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. Please add the hospital discharge date for events sepsis, acute kidney injury, and diarrhea in the eCRF.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:44:38
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Related (NOT RELATED)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Related (NOT RELATED)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' answered with 'Updated to not applicable ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:14:06
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:13:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:13:19
User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:30
Query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:42:16
User opened query 'PV Query: As the last dose of study drug was given on 30 Sep 2020 , please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:39:59
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'None (NONE)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:03:44
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'ConMed 8 and 9 are relative to AE' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 22:19:00
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:00:58
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'I'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:38:48
User closed query 'PV Query: Please provide the final event outcome for events sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:23
Query 'PV Query: Please provide the final event outcome for events sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' answered with 'this is final at this time- no update on outcome' (Site from Safety).	Samantha Wheeler (b) (4) (b) (4)	24 Nov 2020 19:16:27
User opened query 'PV Query: Please provide the final event outcome for events sepsis, acute kidney injury, diarrhea, left upper lobe pneumonia and (diarrhea with) dehydration.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:02
Query 'PV Query: Please provide the final event outcome for event ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:42:12
User opened query 'PV Query: Please provide the final event outcome for event ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:38:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = HYPERTENSION, AND CABG. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 08:11:56
Query 'Per DM CLR: SAE Narrative = HYPERTENSION, AND CABG. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Med HX updated with hypertension and CABG' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:13:46
User opened query 'Per DM CLR: SAE Narrative = HYPERTENSION, AND CABG. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:29:10
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)	25 Nov 2020 21:29:20
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:18
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 21:29:16
User closed query 'PV Query: Please provide treatment given for the events sepsis, acute kidney injury, diarrhea, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. 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 21:29:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the subject experienced gastrointestinal bleed. If yes, please consider reported as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:14
User closed query 'PV Query: Please clarify if the sepsis was secondary to gastroenteritis or the reported pneumonia.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 21:29:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:53
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 'will send.' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 19:36:15
Query 'PV Query: Please clarify if the sepsis was secondary to gastroenteritis or the reported pneumonia.' answered with 'sepsis is secondary to gastroenteritis.' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 19:29:55
Query 'PV Query: Please confirm if the subject experienced gastrointestinal bleed. If yes, please consider reported as separate AE/SAE.' answered with 'gastrointestinal bleed not noted on discharge summary' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 19:26:57
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'updated' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 19:23:33
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:23:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. patient does have underlying conditions such as diabetes, high cholesterol, hypertension, and CABG.' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 19:23:00
Query 'PV Query: Please provide treatment given for the events sepsis, acute kidney injury, diarrhea, acute hyponatremia, hypokalemia, and (diarrhea with dehydration. 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 'all medications that were found within medical record have been reported in EDC' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 18:31:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'where will this information be reported?' (Site from Safety).	Samantha Wheeler (b) (4)	24 Nov 2020 18:30:30
User opened query 'PV Query: Please clarify if the sepsis was secondary to gastroenteritis or the reported pneumonia.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:45:10

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject experienced gastrointestinal bleed. If yes, please consider reported as separate AE/SAE.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:44:50
User opened query 'PV Query: Please provide treatment given for the events sepsis, acute kidney injury, diarrhea, acute hyponatremia, hypokalemia, and (diarrhea with) dehydration. 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)	19 Nov 2020 22:44:15
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)	19 Nov 2020 22:44:04
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:43:51
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)	19 Nov 2020 22:43:42
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)	19 Nov 2020 22:42:08
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:42:05
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)	19 Nov 2020 22:42:01
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)	19 Nov 2020 22:41:07

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:40:36
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)	19 Nov 2020 22:40:12
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '74 y/o male who received second dose of product on 9/30 without incident and was seen for routine f/u on 11/03 and reported no symptoms who was admitted to WFBMC on 11/10 with diagnosis of gastroenteritis with associated sepsis, acute kidney injury, and possible GI bleed. He had reported feeling tired with headaches and muscle aches on 11/09 and was seen for a sick visit. A PCR for Covid-19 was performed at the time was negative. On telephone f/u on 11/10, he reported increased fatigue and development of diarrhea with black stool. We recommended going to EDC (which had also been recommended by PCP). He was admitted from the ED and diagnosed as above.'	Kaitlyn Van Leuvan (b) (4)	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 19:31:23

US3762161

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 19:31:23

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:48:40
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	16 Nov 2020 14:48:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User coded data point as SOC: Renal and urinary disorders, HLT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute kidney injury - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 19:46:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Nov 2020 19:46:51
Data point term sent to Coder	System	13 Nov 2020 19:45:34
User entered 'ACUTE KIDNEY INJURY'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '10 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	17 Nov 2020 20:42:10
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:47:28
	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'per CDM RQ: please remove data from this field' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:58:13
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
Query 'per CDM RQ: please remove data from this field' answered with 'Data has been removed' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:16:53
DataPoint Un-verified.	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:13
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	19 Nov 2020 21:31:13
User opened query 'per CDM RQ: please remove data from this field' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:51:54
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).	(b) (4), (b) (6)	19 Nov 2020 17:27:00
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'start time is unknown' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:47:38
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Nov 2020 19:45:14
User entered '00:00'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 21:31:13
User entered '10 Nov 2020 00:00'	System	17 Nov 2020 20:42:10
User entered '09 Nov 2020 00:00'	System	13 Nov 2020 19:47:28
User entered '10 Nov 2020 00:00'	System	13 Nov 2020 19:45:14

US3762161

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:18:16
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:16:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 19:16:57
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 19:20:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Nov 2020 19:20:52
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:18:16
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	24 Nov 2020 19:16:57
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:16:57
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 19:16:57
DataPoint Verified.	(b) (4)	24 Nov 2020 19:16:57
	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:45:14

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 17:22:37
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
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 'Hospital admission date updated' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:46:49
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	13 Nov 2020 19:45:14
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:20
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:17:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:47:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:47:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:47:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:45:14
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:47:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:47:28
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:47:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:45:14
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:17:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:17:38
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:47:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:47:28
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:47:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:45:14
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Form: Adverse Events (2)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Nov 2020 19:47:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Nov 2020 19:45:14
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:47:28
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:53
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:20:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 19:20:52
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:47:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 19:47:28
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:47:28
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 19:45:14
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CREATININE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:14:40
Query 'Per DM CLR: SAE Narrative = CREATININE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Please clarify each each day of blood work up needs to be documented or just once.	(b) (4), (b) (6)	10 Mar 2021 14:37:22
' (Site from DM).		
User opened query 'Per DM CLR: SAE Narrative = CREATININE. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:29:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:41
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 20:20:07
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. Creatinine: 11/10/20 17:59= 1.75 11/11/20 06:41= 1.32 11/12/07:02= 1.41 11/13/20 06:15= 1.53 11/14/20 08:01= 1.41' reason for change: Data Entry Error DataPoint Verified.	Samantha Wheeler (b) (4) (b) (4)	24 Nov 2020 20:20:07
	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 19:46:28
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 19:46:28

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[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:46:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 19:45:14
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:45:14

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:45:14

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:45:14

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

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:45:14

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:18
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	16 Nov 2020 14:49:13

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 14:33:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	18 Nov 2020 14:33:06
Data point term sent to Coder	System	18 Nov 2020 14:32:03
User closed query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' (Site from System).	System	18 Nov 2020 14:32:02
Query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' answered with 'seperated' (Site from System).	Samantha Wheeler (b) (4)	18 Nov 2020 14:32:02
User entered 'DIARRHEA' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 14:31:52
User opened query 'For coding purposes, please split DIARRHEA WITH DEHYDRATION into separate entries. 1. DIARRHEA and 2. [DIARRHEA WITH] DEHYDRATION' (Site from System).	Coder Import (b) (4)	18 Nov 2020 14:30:05
Data point term sent to Coder	System	18 Nov 2020 14:20:55
DataPoint Un-verified.	Samantha Wheeler (b) (4)	18 Nov 2020 14:20:18
Coding entries removed.	(b) (4)	
	Samantha Wheeler (b) (4)	18 Nov 2020 14:20:18
User entered 'diarrhea with dehydration' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:26:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 23:26:35
Data point term sent to Coder	System	13 Nov 2020 19:49:41

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Possible GI Bleed'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '9 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:48:40

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
DataPoint Un-verified.	Samantha Wheeler (b) (4)	18 Nov 2020 20:07:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wheeler (b) (4)	18 Nov 2020 20:07:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:09:21
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	18 Nov 2020 20:09:21
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:07:18
DataPoint Un-verified.	Samantha Wheeler (b) (4)	18 Nov 2020 20:07:18
User entered '15 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 20:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:26:39
	(b) (4), (b) (6)	17 Nov 2020 21:54:25
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 'Hospital admission date updated ' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 19:51:49
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	13 Nov 2020 19:48:40
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '10 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:30:33
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:30:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:30:33
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:30:33
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:12:20
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'we did not see any con meds or con procedures for this indication as it was part of a hospitalization with many SAEs' (Site from DM).	Samantha Wheeler (b) (4)	09 Apr 2021 15:43:57
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 03:52:18
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Mar 2021 14:10:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 14:10:07
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 14:10:07
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Mar 2021 14:09:43
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted; however ConMed page does not seem to have been updated. Please review and reconcile. Thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 17:11:27
Query 'Per CDM Re-Query: Site response noted; however ConMed page does not seem to have been updated. Please review and reconcile. Thank you.' answered with 'updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 14:09:50
User opened query 'Per CDM Re-Query: Site response noted; however ConMed page does not seem to have been updated. Please review and reconcile. Thank you.' (Site from DM). User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 14:09:43
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'ConMeds have been updated per AE' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 14:09:43
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:05:21
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:05:21
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'ConMeds have been updated per AE' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 22:19:52
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:01:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
DataPoint Un-verified.	Samantha Wheeler (b) (4)	18 Nov 2020 20:09:21
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 20:09:21
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:54:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 19:51:32
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Nov 2020 19:51:32
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 19:51:32
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Nov 2020 19:48:40
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 19:48:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Nov 2020 19:48:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 19:48:40

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:55:09
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	18 Nov 2020 14:55:00

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Lobar pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:32:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:32:08
Data point term sent to Coder	System	18 Nov 2020 14:04:45
User entered 'Left Upper lobe pneumonia'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:53
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:53
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
User entered '18 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
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	18 Nov 2020 14:04:31
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	18 Nov 2020 14:04:06
User entered 'Yes (Y)'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		18 Nov 2020 14:04:31
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		18 Nov 2020 14:04:31
User entered '1' reason for change: Data Entry Error Samantha Wheeler	(b) (4)	18 Nov 2020 14:04:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	18 Nov 2020 14:04:06
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:48:04
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:31:02
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'None (NONE)'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'I'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:53
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 19:19:14
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CT CHEST SCAN WITHOUT CONTRAST WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:19:47
Query 'Per DM CLR: SAE Narrative = CT CHEST SCAN WITHOUT CONTRAST WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Con procedures updated ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:49:57
User opened query 'Per DM CLR: SAE Narrative = CT CHEST SCAN WITHOUT CONTRAST WAS PERFORMED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 00:30:54
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:26:41
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	24 Nov 2020 20:13:19

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. ct chest scan without contrast was performed' reason for change: Data Entry Error DataPoint Verified.	Samantha Wheeler (b) (4) (b) (4)	24 Nov 2020 20:13:19
	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 14:05:10
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 14:05:10

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 14:05:10
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 14:04:06
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 14:04:06

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:56:23
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	18 Nov 2020 14:56:14

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:26:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:26:06
Data point term sent to Coder	System	18 Nov 2020 14:24:58
User entered 'Acute hyponatremia'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:24:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 14:24:56
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:56
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:24:29
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '1'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:07:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:07:52
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'None (NONE)'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:24:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
User closed query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:05:50
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:41:34
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:41:34
Query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' answered with 'Con Med updated ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:41:07
User opened query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:15:24
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '1'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:41:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:41:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:24:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 14:25:49
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 14:25:49
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:25:49
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 14:24:29
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 14:24:29

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:58:42
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	18 Nov 2020 14:58:37

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
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)	18 Nov 2020 14:32:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 14:32:06
Data point term sent to Coder	System	18 Nov 2020 14:31:02
User entered 'hypokalemia'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Grade 1/Mild (Grade 1/Mild)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '1'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:08:46
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:31:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 14:31:05
User entered 'None (NONE)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 14:31:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 14:30:13
User entered empty.	System	18 Nov 2020 14:30:13
	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:06:46
Query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' answered with 'added to narrative ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 19:44:27
User opened query 'Per DM CLR: Is this AE serious? = Yes. Please review and please note, there is no listed treatment for this AE and treatment is expected. Please update to record the corresponding treatment as applicable. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:16:03
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'I'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:44:20
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE. For hypokalemia no medication was administered.' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:44:20
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.'	Samantha Wheeler (b) (4)	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:30:13

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 14:30:13

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:59:43
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	18 Nov 2020 14:59:36

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query ' Per DM CLR: Please note this AE overlaps with AE #3 (DIARRHEA). Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM). Query '	(b) (4), (b) (6)	15 Mar 2021 13:20:40
Per DM CLR: Please note this AE overlaps with AE #3 (DIARRHEA). Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'Medical summary documented with both events ' (Site from DM).		
User opened query ' Per DM CLR: Please note this AE overlaps with AE #3 (DIARRHEA). Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 00:32:31
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder User entered '[Diarrhea with] Dehydration'	Coder Import (b) (4) (b) (4) Coder Import (b) (4) (b) (4) System Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:46:06 18 Nov 2020 14:46:06 18 Nov 2020 14:35:11 18 Nov 2020 14:34:31

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '09 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:34:31

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:18:16
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:17:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 19:17:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:18:16
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 19:18:05
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Nov 2020 19:18:05
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	24 Nov 2020 19:17:37
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:17:37
User entered '15 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 19:17:37
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 14:34:31

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'I'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:09:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered 'None (NONE)'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise , clarify.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 16:22:22
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise , clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 17:50:59
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:49:21
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:49:21
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise , clarify.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 03:15:04
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '1'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
DataPoint Un-verified.	(b) (4), (b) (6)	25 Jan 2021 17:49:21
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 17:49:21
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 19:18:16
DataPoint Un-verified.	Samantha Wheeler (b) (4)	24 Nov 2020 19:18:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Samantha Wheeler (b) (4)	24 Nov 2020 19:18:05
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:34:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 14:34:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:51
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 14:34:31
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:46
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.'	Samantha Wheeler (b) (4)	18 Nov 2020 14:34:31

US3762161

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 14:34:31

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:33:40
User entered 'USA-US130-2020-mRNA-1273-P301000004'	System	29 Dec 2020 15:33:27
User entered 'New'	(b) (4), (b) (6)	29 Dec 2020 15:33:27

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 17:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 17:55:22
Data point term sent to Coder	System	28 Dec 2020 17:54:56
User entered 'urinary tract infection'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'No (N)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'No (N)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '24 Dec 2020'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
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	28 Dec 2020 17:54:50
User entered empty; reason for change Data Entry Error	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:50
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	28 Dec 2020 17:54:29
User entered '00:00'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 17:54:50
User entered '24 Dec 2020 00:00'	System	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

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[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:10:33
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing per patient report' (Site from DM).	Samantha Wheeler (b) (4)	09 Mar 2021 15:23:18
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:25:37
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Requery: 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). DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 20:17:44
	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered empty.	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 17:53:22
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 'pt did not report end time ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:12:34
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:46:25
User entered empty.	Samantha Wheeler (b) (4) (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:23:56
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 'summary sent ' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 20:08:58
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
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)	05 Jan 2021 14:46:13
User entered 'I'	Samantha Wheeler (b) (4) (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '24 Dec 2020'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm discharge date as conflicting date of 25 Dec 2020 was reported in discharge summary.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 17:53:36
	(b) (4), (b) (6)	10 Mar 2021 19:29:34
Query 'PV Query: Please confirm discharge date as conflicting date of 25 Dec 2020 was reported in discharge summary.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 14:28:06
	(b) (4), (b) (6)	10 Mar 2021 14:15:19
User entered '25 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 14:15:19
User opened query 'PV Query: Please confirm discharge date as conflicting date of 25 Dec 2020 was reported in discharge summary.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 20:29:49
	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '26 Dec 2020'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'No (N)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered empty.	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Not Related (NOT RELATED)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered 'Not Applicable (NOT APPLICABLE)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '0'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered '1'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Concomitant Procedure is checked, however, no data is present on Concomitant Procedure eCRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:07:29
Query 'Per CDM: Concomitant Procedure is checked, however, no data is present on Concomitant Procedure eCRF. Please update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 20:02:29
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User opened query 'Per CDM: Concomitant Procedure is checked, however, no data is present on Concomitant Procedure eCRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 18:35:48
User entered 'I'	Samantha Wheeler (b) (4) (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 20:18:20
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)	12 Mar 2021 19:44:11
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 'patient has appointment with urologist next month to confirm and seek treatment ' (Site from Safety).	Samantha Wheeler (b) (4)	11 Mar 2021 19:43:44
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:46:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:15
User entered empty.	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide dates for most recent episode of kidney stones prior to the event and details of stent.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 17:53:40
Query 'PV Query: Please provide dates for most recent episode of kidney stones prior to the event and details of stent.' answered with 'narrative updated ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'PATIENT HAS BEEN EXPERIENCING KIDNEY STONES AND HAS GONE THROUGH TO GET A STENT ETC. PATIENT HAS COMPLAINED OF PAIN WITH URINATION AND WENT TO THE EMERGENCY ROOM. ALL CULTURES WERE NEGATIVE. AND PATIENT WAS STARTED ON ANTIBIOTIC. URINALYSIS ABNORMAL, PRESENTING WITH MODERATE BACTERIA, LARGE AMOUNT OF BLOOD. URINE PROTEIN 100MG/DL, YEAST PRESENT AS WELL.	(b) (4), (b) (6)	10 Mar 2021 14:34:07
PT REPORTS MOST RECENT EPISODE OF KIDNEY STONES IN 2013.' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	10 Mar 2021 14:33:49
User entered 'PATIENT HAS BEEN EXPERIENCING KIDNEY STONES AND HAS GONE THROUGH TO GET A STENT ETC. PATIENT HAS COMPLAINED OF PAIN WITH URINATION AND WENT TO THE EMERGENCY ROOM. ALL CULTURES WERE NEGATIVE. AND PATIENT WAS STARTED ON ANTIBIOTIC. URINALYSIS ABNORMAL, PRESENTING WITH MODERATE BACTERIA, LARGE AMOUNT OF BLOOD. URINE PROTEIN 100MG/DL, YEAST PRESENT AS WELL.	(b) (4), (b) (6)	10 Mar 2021 14:15:19
Pt reports most recent episode of kidney stones in' reason for change: Data Entry Error		10 Mar 2021 14:15:19

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide dates for most recent episode of kidney stones prior to the event and details of stent.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 20:30:17
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:24:00
User closed query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 14:23:58
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:43
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 was not tested during this SAE' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 20:13:40
Query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 20:12:08
User entered 'PATIENT HAS BEEN EXPERIENCING KIDNEY STONES AND HAS GONE THROUGH TO GET A STENT ETC. PATIENT HAS COMPLAINED OF PAIN WITH URINATION AND WENT TO THE EMERGENCY ROOM. ALL CULTURES WERE NEGATIVE. AND PATIENT WAS STARTED ON ANTIBIOTIC. Urinalysis abnormal, presenting with moderate bacteria, large amount of blood. Urine protein 100mg/dL, yeast present as well.' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:11:04
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 20:00:04

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT HAS BEEN EXPERIENCING KIDNEY STONES AND HAS GONE THROUGH TO GET A STENT ETC. PATIENT HAS COMPLAINED OF PAIN WITH URINATION AND WENT TO THE EMERGENCY ROOM. ALL CULTURES WERE NEGATIVE. AND PATIENT WAS STARTED ON ANTIBIOTIC.' reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 20:00:04
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)	05 Jan 2021 14:46:56
User opened query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 14:46:47
User entered 'Patient has been experiencing kidney stones and has gone through to get a stent etc. Patient has complained of pain with urination and went to the emergency room. All cultures were negative. and patient was started on antibiotic.'	Samantha Wheeler (b) (4)	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 17:54:29

US3762161

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Dec 2020 17:54:29

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User entered '0'	System	28 Dec 2020 17:54:29

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 15:23:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:01:50
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:00:49
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:00:46
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:00:32
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 19:00:03
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:59:59
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:59:37
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:59:34
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 18:59:30
User entered 'USA-US130-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	11 Mar 2021 18:26:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Faecal abnormalities NEC, PT: Faeces discoloured, LLT: Stool black - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:02:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:02:50
Data point term sent to Coder	System	10 Mar 2021 14:02:12
User entered 'Black Stool'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User entered empty.	System	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '11 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User entered empty.	System	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	10 Mar 2021 19:27:51
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	10 Mar 2021 19:27:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:27:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
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).		10 Mar 2021 19:27:51
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).		10 Mar 2021 19:27:51
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:27:51
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	10 Mar 2021 19:27:40
User entered '1'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:27:40
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:27:40
User entered '15 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 19:27:40
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'l'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User closed query 'Per DM CLR: Narrative = DIAGNOSIS OF GASTROENTERITIS. 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)	21 Apr 2021 07:59:08
Query 'Per DM CLR: Narrative = DIAGNOSIS OF GASTROENTERITIS. 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 'on discharge there was no mention of gastroenteritis- this is the only mention of it' (Site from DM).	Samantha Wheeler (b) (4)	09 Apr 2021 15:45:07
User opened query 'Per DM CLR: Narrative = DIAGNOSIS OF GASTROENTERITIS. 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 03:51:46
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Mar 2021 14:10:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Mar 2021 14:10:39

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
User entered '74 Y/O MALE WHO RECEIVED SECOND DOSE OF PRODUCT ON 9/30 WITHOUT INCIDENT AND WAS SEEN FOR ROUTINE F/U ON 11/03 AND REPORTED NO SYMPTOMS WHO WAS ADMITTED TO WFBMC ON 11/10 WITH DIAGNOSIS OF GASTROENTERITIS WITH ASSOCIATED SEPSIS, ACUTE KIDNEY INJURY, AND POSSIBLE GI BLEED. HE HAD REPORTED FEELING TIRED WITH HEADACHES AND MUSCLE ACHES ON 11/09 AND WAS SEEN FOR A SICK VISIT. A PCR FOR COVID-19 WAS PERFORMED AT THE TIME WAS NEGATIVE. ON TELEPHONE F/U ON 11/10, HE REPORTED INCREASED FATIGUE AND DEVELOPMENT OF DIARRHEA WITH BLACK STOOL. WE RECOMMENDED GOING TO EDC (WHICH HAD ALSO BEEN RECOMMENDED BY PCP). HE WAS ADMITTED FROM THE ED AND DIAGNOSED AS ABOVE.' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 14:10:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Mar 2021 14:01:43
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User entered '0'	System	10 Mar 2021 19:27:15
User entered '1'	System	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User entered 'I'	System	10 Mar 2021 14:01:43

US3762161

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:39:10
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:37:43
User entered '0'	System	10 Mar 2021 14:01:43

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Folder: Adverse Events

Form: Adverse Events (11)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:03:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Mar 2021 14:03:52
Data point term sent to Coder	System	10 Mar 2021 14:03:18
User entered 'Fatigue'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '11 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:03:00

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 14:03:00

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:19:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:05:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:05:07
Data point term sent to Coder	System	10 Mar 2021 14:04:19
User entered 'Minor cough'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 14:04:09

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:06:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 14:06:58
Data point term sent to Coder	System	10 Mar 2021 14:06:21
User entered 'Headache'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '5 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 14:05:38

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Mar 2021 14:07:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	10 Mar 2021 14:07:50
Data point term sent to Coder	System	10 Mar 2021 14:07:21
User entered 'Body ache'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '9 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered '0'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:29:34
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Mar 2021 14:06:29

US3762161

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 09:43:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Mar 2021 14:06:29

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:20
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per ETRTR: Please ensure medication for SAEs "Sepsis" and "Acute Kidney Injury" is entered on the Concomitant Medication page or update the action taken. Thanks! ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 14:19:17
Query 'Per ETRTR: Please ensure medication for SAEs "Sepsis" and "Acute Kidney Injury" is entered on the Concomitant Medication page or update the action taken. Thanks! ' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 13:32:47
User opened query 'Per ETRTR: Please ensure medication for SAEs "Sepsis" and "Acute Kidney Injury" is entered on the Concomitant Medication page or update the action taken. Thanks! ' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:22:21
Query 'Per ETRTR: Please ensure medication for SAE "Sepsis" is entered on the Concomitant Medication page or update the action taken. Thanks!' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:21:38
User opened query 'Per ETRTR: Please ensure medication for SAE "Sepsis" is entered on the Concomitant Medication page or update the action taken. Thanks!' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:02:24
Query 'Per ETRTR: Please ensure medication for SAE "Sepsis" is entered on the Concomitant Medication page or update the action taken. Thanks!' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:02:06
User opened query 'Per ETRTR: Please ensure medication for SAE "Sepsis" is entered on the Concomitant Medication page or update the action taken. Thanks!' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 16:01:57
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:13:08
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:52:58

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Mar 2021 18:08:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 18:08:55
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	10 Mar 2021 18:07:54 10 Mar 2021 18:07:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:36:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:36:23
Data point term sent to Coder User entered 'Lisinopril'	System Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:54:32 03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 18:51:44
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:20:46
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:45:44
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 17:45:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:45:38
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 20:16:55
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:07:27
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Mar 2021 18:07:27
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'High cholesterol'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '10'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'un Aug 2000'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 17:53:59

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
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)	03 Nov 2020 17:56:26
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 Nov 2020 17:56:26
Data point term sent to Coder	System	03 Nov 2020 17:55:34
User entered 'Atorvastatin'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'High cholesterol'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '80'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'UN Feb 2007' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:57:40
User entered 'un Feb 2017'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 17:55:02

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 17:57:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 17:57:23
Data point term sent to Coder	System	03 Nov 2020 17:56:35
User entered 'metformin'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Type II DIABETES'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '1000' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:57:24
User entered '100'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'UN Feb 2007' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:57:24
User entered 'un Feb 2017'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 17:55:52

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
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)	30 Mar 2021 14:10:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:10:45
Data point term sent to Coder Coding entries removed.	System	26 Mar 2021 19:13:17
	Samantha Wheeler (b) (4)	26 Mar 2021 19:12:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
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)	03 Nov 2020 18:00:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:00:22
Data point term sent to Coder	System	03 Nov 2020 17:59:41
User entered 'Gabapentin'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 18:51:44
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:21:05
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:46:25
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 17:46:18
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:46:18
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 19:36:58
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:48:36
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'updated as much as possible ' (Site from DM).	Samantha Wheeler (b) (4)	26 Mar 2021 19:12:59
DataPoint Un-verified.	Samantha Wheeler (b) (4)	26 Mar 2021 19:12:51
User entered 'polyNEUROPATHY in feet' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	26 Mar 2021 19:12:51
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:19:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Neuropathy'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '800'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'four times daily (QID)'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'un UNK 2010'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 18:02:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 18:02:22
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 18:02:22
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 18:02:22
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan	03 Nov 2020 17:59:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered '4'	System	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered '1'	System	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:19
User entered '804 (804)'	System	03 Nov 2020 17:59:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 16:15:10
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)	03 Nov 2020 18:01:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 18:01:23
Data point term sent to Coder	System	03 Nov 2020 18:00:41
User entered 'Aspirin'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Heart health'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '325'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'un UNK 2005'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 18:00:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:03:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:03:27
Data point term sent to Coder	System	03 Nov 2020 18:02:47
User entered 'Humalog'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 18:51:44
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 14:22:11
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:48:16
DataPoint Un-verified.	(b) (4), (b) (6)	21 Jan 2021 17:48:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Jan 2021 17:48:07
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 19:40:22
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Type II Diabetes'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '100'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'IU (IU)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'four times daily (QID)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Nov 2020 18:02:51
User entered 'Un UNK 1998' reason for change: Data Entry Error	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:51
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Nov 2020 18:02:23
User entered 'uu UNK 1998' (non-conformant).	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 18:02:23

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 18:06:23
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 Nov 2020 18:06:23
Data point term sent to Coder	System	03 Nov 2020 18:05:49
User entered 'Levemir'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Type II Diabetes'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '56'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'IU (IU)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'once daily (QD)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'un UNK 2007'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Kaitlyn Van Leuvan (b) (4)	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 18:05:19

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR, PRODUCTSYNONYM: OMNICEF [CEFDINIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Jan 2021 23:36:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Jan 2021 23:36:53
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
Data point term sent to Coder	System	14 Jan 2021 14:18:54
Coding entries removed.	(b) (4), (b) (6)	14 Jan 2021 14:18:18
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: CEFDINIR, PRODUCTSYNONYM: OMNICEF [CEFDINIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 03:21:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 03:21:05
Data point term sent to Coder	System	24 Nov 2020 19:55:49
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	24 Nov 2020 19:55:25

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'iupdated' (Site from System).	Samantha Wheeler (b) (4)	24 Nov 2020 19:55:25
DataPoint Un-verified.	(b) (4)	
User entered 'OMNICEF	Samantha Wheeler (b) (4)	24 Nov 2020 19:55:08
[cefdinir]' reason for change: Data Entry Error	(b) (4)	
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 13:26:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
Data point term sent to Coder	System	18 Nov 2020 14:37:13
User entered 'omnicef'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 14:18:18
User entered 'PNEUMONIA and sepsis' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 14:18:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'pneumonia'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '300'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'twice daily (BID)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
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)	23 Feb 2021 13:58:39
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).	Samantha Wheeler (b) (4)	22 Feb 2021 19:43:18
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:43:12
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:43:12
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)	30 Jan 2021 10:32:21
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:43:12
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:43:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:36:44
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User entered '2'	System	18 Nov 2020 14:36:44

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User entered '1'	System	18 Nov 2020 14:36:44

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:09
User entered '804 (804)'	System	18 Nov 2020 14:36:44

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 15:30:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 15:30:55
Data point term sent to Coder	System	14 Jan 2021 14:18:53
Coding entries removed.	(b) (4), (b) (6)	14 Jan 2021 14:18:32
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE HYCLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 12:03:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 12:03:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
Data point term sent to Coder	System	18 Nov 2020 14:49:22
User entered 'doxycycline hyclate'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 14:18:32
User entered 'PNEUMONIA and sepsis' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 14:18:32
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'pneumonia'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '100'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'twice daily (BID)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
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)	23 Feb 2021 13:57:17
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 'corrected' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:19:13
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:19:08
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:19:08
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)	30 Jan 2021 10:28:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'Yes (Y)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:19:08
	(b) (4)	
User entered '18 Nov 2020' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:19:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:15:10
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 14:48:55
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User entered '2'	System	18 Nov 2020 14:48:55

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User entered '1'	System	18 Nov 2020 14:48:55

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:00:13
User entered '804 (804)'	System	18 Nov 2020 14:48:55

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 21:50:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	18 Apr 2021 21:50:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Query 'Per DM CLR: This Conmed is given for the AE#7. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:06:33
User opened query 'Per DM CLR: This Conmed is given for the AE#7. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 20:58:57
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)	27 Jan 2021 00:14:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:14:53
Data point term sent to Coder	System	26 Jan 2021 19:40:47
Coding entries removed.	(b) (4), (b) (6)	26 Jan 2021 19:40:43

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
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)	15 Jan 2021 17:20:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Jan 2021 17:20:53
Data point term sent to Coder	System	14 Jan 2021 14:18:54
Coding entries removed.	(b) (4), (b) (6)	14 Jan 2021 14:18:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
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)	19 Nov 2020 03:39:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:39:57
Data point term sent to Coder	System	18 Nov 2020 19:50:49
User entered 'sodium chloride'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 19:49:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR : Please review "Other Action Taken" field in AE-Dehydration eCRF as it does not reflect this Con Med for AE #7. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:58:18
Query 'Per DM CLR : Please review "Other Action Taken" field in AE-Dehydration eCRF as it does not reflect this Con Med for AE #7. Please reconcile and correct response as appropriate. ' answered with 'dehydration does show conmed taken' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:44:56
User opened query 'Per DM CLR : Please review "Other Action Taken" field in AE-Dehydration eCRF as it does not reflect this Con Med for AE #7. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 10:33:55
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:55:18
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 19:40:43
User entered 'DEHYDRATION, Hyponatremia, AND ACUTE KIDNEY INJURY' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 19:40:43
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 14:18:54
User entered 'DEHYDRATION and acute kidney injury' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 14:18:54
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'dehydration'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '100'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Other (OTHER)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'mL/hr'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'other (OTHER)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'continuous'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Intravenous (INTRAVENOUS)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '11 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:49:54
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User entered empty.	System	18 Nov 2020 19:49:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User entered empty.	System	18 Nov 2020 19:49:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:38
User entered empty.	System	18 Nov 2020 19:49:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
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)	18 Nov 2020 19:51:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Nov 2020 19:51:48
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:50:49
User entered 'acetaminophen'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR-RQ: Response noted. However, this is not consider a solicited event as the start and stop date of the HEADACHE does not fit within the corresponding time frame, since it started after the 7-day post vaccination period for collecting solicited events. Please review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 08:17:28
Query 'Per DM CLR-RQ: Response noted. However, this is not consider a solicited event as the start and stop date of the HEADACHE does not fit within the corresponding time frame, since it started after the 7-day post vaccination period for collecting solicited events. Please review and update as appropriate.' answered with 'Headache added to AE log ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:07:48
User opened query 'Per DM CLR-RQ: Response noted. However, this is not consider a solicited event as the start and stop date of the HEADACHE does not fit within the corresponding time frame, since it started after the 7-day post vaccination period for collecting solicited events. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:39:00
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:29:41
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'This is a solicited event ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 17:50:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 15:53:45
	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'headache'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '1000'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:56:34
Query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:45:26
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:45:22
User entered 'once (ONCE)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:45:22
User opened query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 10:27:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'once daily (QD)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Oral (ORAL)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:50:42
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User entered empty.	System	22 Feb 2021 19:45:22
User entered '1'	System	18 Nov 2020 19:50:42

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User entered empty.	System	22 Feb 2021 19:45:22
User entered '1'	System	18 Nov 2020 19:50:42

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:43
User entered empty.	System	22 Feb 2021 19:45:22
User entered '804 (804)'	System	18 Nov 2020 19:50:42

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
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)	18 Nov 2020 19:55:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 19:55:48
Data point term sent to Coder	System	18 Nov 2020 19:54:53
User entered 'zofran'	Samantha Wheeler (b) (4) (b) (4)	18 Nov 2020 19:54:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:47:56
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:47:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:17:38
Query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' answered with 'pt was given this during hospitalization. Please see AE log for further details ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:08:39
User opened query 'Per DM CLR: Prophylaxis = YES. Please review Indication and update to reflect the term Prophylaxis and the medical condition prevented. Per CCG, If taken as prophylaxis, we recommend reporting as "Prophylaxis for...". Please update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 17:39:45
User closed query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:59:05
Query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate.' answered with 'this was a prophylactic..didnt actually occur ' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:48:58

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Jan 2021 10:39:21
	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'nausea'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '4'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:59:12
Query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:49:42
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:49:38
User entered 'as needed (PRN)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:49:38
User opened query 'Per DM CLR: Please review the Frequency = ONCE DAILY. However, the medication timeframe is only 1 day, please review if "Once" is a more appropriate recording. Review and update Frequency as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 10:39:38
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'once daily (QD)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Intravenous (INTRAVENOUS)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '10 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:54:09
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User entered empty.	System	22 Feb 2021 19:49:38
User entered 'I'	System	18 Nov 2020 19:54:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User entered empty.	System	22 Feb 2021 19:49:38
User entered '1'	System	18 Nov 2020 19:54:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:48
User entered empty.	System	22 Feb 2021 19:49:38
User entered '804 (804)'	System	18 Nov 2020 19:54:09

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:56:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 19:56:47
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:55:55
User entered 'piperacillin-tazobactam'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'pneumonia'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '3.375'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'g (g)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'four times daily (QID)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Intravenous (INTRAVENOUS)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '12 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:10
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User entered '4'	System	18 Nov 2020 19:55:10

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User entered '1'	System	18 Nov 2020 19:55:10

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:51
User entered '804 (804)'	System	18 Nov 2020 19:55:10

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 03:36:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 03:36:58
	(b) (4)	
Data point term sent to Coder	System	18 Nov 2020 19:55:55
User entered 'vancomycin'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'pneumonia'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '1500'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'mg (mg)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'once daily (QD)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'Intravenous (INTRAVENOUS)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '13 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '0'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered 'No (N)'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User entered '15 Nov 2020'	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:06:12
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:55:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:55:58
User entered 'No (N)' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:58
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:55:53
User entered empty.	Samantha Wheeler (b) (4)	18 Nov 2020 19:55:53
	(b) (4)	

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User entered '1'	System	18 Nov 2020 19:55:53

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User entered '1'	System	18 Nov 2020 19:55:53

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:55
User entered '804 (804)'	System	18 Nov 2020 19:55:53

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:36
Data point term sent to Coder	System	21 Dec 2020 18:21:55
User entered 'Flomax'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 13:57:40
Query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' answered with 'con history' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 19:52:13
User opened query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 10:30:46
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Kidney stones'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0.4'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

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

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Dec 2020 18:21:49

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 11:21:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 11:21:46
Data point term sent to Coder Coding entries removed.	System Samantha Wheeler (b) (4)	22 Feb 2021 19:53:34 22 Feb 2021 19:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 15:41:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 15:41:55
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	14 Jan 2021 14:23:57 14 Jan 2021 14:23:30
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:38

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[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.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:38
Data point term sent to Coder	System	21 Dec 2020 18:22:55
User entered 'Gentamicin'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 14:23:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per CDM Re-Query. Site response noted; however "Kidney Stone Removal" indicates the effect of the medication. Please review and update the indication to the condition the medication if used for (eg. Kidney Stone). Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:29:10
Query 'Per CDM Re-Query. Site response noted; however "Kidney Stone Removal" indicates the effect of the medication. Please review and update the indication to the condition the medication if used for (eg. Kidney Stone). Thank you. ' answered with 'updated' (Site from DM).	Samantha Wheeler (b) (4)	22 Feb 2021 19:52:56
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:52:52
User entered 'KIDNEY STONE' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:52:52
User opened query 'Per CDM Re-Query. Site response noted; however "Kidney Stone Removal" indicates the effect of the medication. Please review and update the indication to the condition the medication if used for (eg. Kidney Stone). Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:47:52
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than to indicate the action/class of the medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:47:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Kidney stone removal' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Jan 2021 14:23:30

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than to indicate the action/class of the medication. Please update as appropriate or provide clarification.' answered with 'Per source this indication is correct' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 17:59:53
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than to indicate the action/class of the medication. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 21:05:31
User entered 'antibiotics'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '270'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'once (ONCE)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '15 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '15 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User entered empty.	System	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User entered empty.	System	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:07
User entered empty.	System	21 Dec 2020 18:22:54

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: AZO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 21:16:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 21:16:03
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 19:53:35
Coding entries removed.	Samantha Wheeler (b) (4)	22 Feb 2021 19:53:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: AZO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:37
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 18:23:56
User entered 'AZO'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
User closed query 'Per DM CLR: Please update the indication to reflect the type of INFECTION. Please reconcile with AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	23 Feb 2021 13:56:53
' (Site from DM).		
Query 'Per DM CLR: Please update the indication to reflect the type of INFECTION. Please reconcile with AE and Med History eCRFs as appropriate.	Samantha Wheeler (b) (4)	22 Feb 2021 19:53:18
' answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Samantha Wheeler (b) (4)	22 Feb 2021 19:53:14
	(b) (4)	
User entered 'kidney stone' reason for change: Data Entry Error	Samantha Wheeler (b) (4)	22 Feb 2021 19:53:14
	(b) (4)	
User opened query 'Per DM CLR: Please update the indication to reflect the type of INFECTION. Please reconcile with AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	30 Jan 2021 10:27:37
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'infection'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
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.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 08:17:49
' (Site from DM).		
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.	(b) (4), (b) (6)	10 Mar 2021 18:11:16
' answered with 'Per pt report this amount is correct '		
(Site from DM).		
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.	(b) (4), (b) (6)	04 Mar 2021 17:39:21
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '97.5'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'three times daily (TID)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '19 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '20 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User entered '3'	System	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User entered '1'	System	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:11
User entered '804 (804)'	System	21 Dec 2020 18:23:39

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:20:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Mar 2021 14:20:25
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 19:54:36
Coding entries removed.	Samantha Wheeler (b) (4)	22 Feb 2021 19:53:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:39
	(b) (4)	
Data point term sent to Coder	System	21 Dec 2020 18:24:57
User entered 'Tramadol'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:47:17
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 08:39:27
Query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' answered with 'taken for kidney stone pain' (Site from DM).	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 19:53:52
DataPoint Un-verified.	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 19:53:41
User entered 'kidney stone' reason for change: Data Entry Error	Samantha Wheeler (b) (4) (b) (4)	22 Feb 2021 19:53:41
User opened query 'Per DM CLR: Please note that there is no AE conditiont recorded that matches this Con Med indication during this time frame. Please review Con Med use and add an AE condition to AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 10:37:51
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Pain at kidney'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '50'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '15 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '20 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User entered empty.	System	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User entered empty.	System	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:16
User entered empty.	System	21 Dec 2020 18:24:46

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
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: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 18:00:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 18:00:23
	(b) (4)	
Data point term sent to Coder	System	28 Dec 2020 18:00:03
User entered 'Cefdinir'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Urinary tract infection'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '300'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '26 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:55:18
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 20:31:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:31:00
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 17:59:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Dec 2020 17:59:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 17:59:18
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 17:59:13
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 18:55:18
DataPoint Un-verified.	(b) (4), (b) (6)	26 Jan 2021 20:31:00
User entered '31 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Jan 2021 20:31:00
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User entered '1'	System	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User entered '1'	System	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:59:21
User entered '804 (804)'	System	28 Dec 2020 17:59:13

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
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)	28 Dec 2020 18:19:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 18:19:21
Data point term sent to Coder	System	28 Dec 2020 18:04:05
User entered 'Gabapentin'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Neuropathy'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '800'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with GABAPENTIN CM#4 (Start date UN UNK 2010- Stop date 24 DEC 2020). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 08:18:02
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with GABAPENTIN CM#4 (Start date UN UNK 2010- Stop date 24 DEC 2020). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.' answered with 'Pt changed frequency ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:12:54
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with GABAPENTIN CM#4 (Start date UN UNK 2010- Stop date 24 DEC 2020). Please consider updating dates if necessary. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 11:21:41
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '24 Dec 2020'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered '0'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 14:25:38
User entered 'No (N)'	(b) (4), (b) (6)	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:43:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Dec 2020 18:03:11

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:43:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:39:20
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:42:48
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:00:56

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:02:11

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Ultrasound of urinary/renal system'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:02:11

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:02:11

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:02:11

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:05:55

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Right Ureteral stent'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:05:55

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Medical History (MH)'	(b) (4), (b) (6)	26 Jan 2021 20:05:55

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:38
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 20:05:55

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:02:58
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Per report this date is correct ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:52:07
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:24:53
User entered '28 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 20:07:04

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:43:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Right Ureteral Stent Removal'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:07:04

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:07:04

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:43:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:41
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:07:04

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User closed query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 10:03:16
Query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'Per medical summary report this date is correct ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:52:29
User opened query 'Per DM CLR: Please review the Date of this procedure/Surgery, as it is out of the expected timeframe with the MH #9 KIDNEY STONES (UN UNK 1995- JAN 1995). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 09:25:07
User entered '15 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 20:07:32

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:43:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Kidney Stone Removal'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 20:07:32

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Medical History (MH)'	(b) (4), (b) (6)	26 Jan 2021 20:07:32

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:43:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 20:07:32

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:43:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 13:51:33

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:43:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'CT CHEST SCAN WITHOUT CONTRAST'	(b) (4), (b) (6)	10 Mar 2021 13:51:33

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:43:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	10 Mar 2021 13:51:33

US3762161

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 09:43:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:29:57
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 13:51:33

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
User entered '12/Nov/2020 15:36'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
User entered '16/Nov/2020 09:49'	System	16 Nov 2020 14:50:05

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 15:00:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:55:37
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:50:05

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:58:38
User entered '18/Nov/2020 15:00'	System	18 Nov 2020 15:00:35

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 13:36:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:58:38
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 15:00:35

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:05:16
User entered '19/Nov/2020 13:36'	System	19 Nov 2020 13:37:07

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 21:29:42
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:05:16
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 13:37:07

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:46:53
User entered '20/Nov/2020 10:40'	System	20 Nov 2020 15:40:44

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 21:29:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:46:53
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 15:40:44

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:49:04
User entered '25/Nov/2020 21:29'	System	25 Nov 2020 21:30:07

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:49:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:46:18
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 21:30:07

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:49:04
User entered '26/Jan/2021 10:45'	System	26 Jan 2021 15:46:05

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:49:04
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 15:46:18
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 15:46:05

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:17:06
User entered '27/Jan/2021 17:39'	System	27 Jan 2021 17:39:53

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:09:53
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:17:06
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 17:39:53

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '11/Mar/2021 12:09'	(b) (4) System	11 Mar 2021 17:09:50

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:09:53
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 17:09:50

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '11/Mar/2021 13:26'	(b) (4) System	11 Mar 2021 18:26:36

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:26:55
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 18:26:36

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered		
'USA-US130-2020-MRNA-1273-P301000001'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Yes (Y)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'No (N)'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'John'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Sanders'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '100 Medical Center Blvd'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'Winston-Salem'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered 'NC'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 15:36:29
User entered '27157'	System	12 Nov 2020 15:35:24

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 21:55:37
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:49:46
User entered 'US'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	11 Mar 2021 19:02:58
User entered '10'	System	11 Mar 2021 18:26:36
User entered '9'	System	11 Mar 2021 17:09:50
User entered '8'	System	27 Jan 2021 17:39:53
User entered '7'	System	26 Jan 2021 15:46:05
User entered '6'	System	25 Nov 2020 21:30:07
User entered '5'	System	20 Nov 2020 15:40:44
User entered '4'	System	19 Nov 2020 13:37:07
User entered '3'	System	18 Nov 2020 15:00:35
User entered '2'	System	16 Nov 2020 14:50:05
User entered '1'	System	12 Nov 2020 15:36:37

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '11/Mar/2021 14:02'	(b) (4) System	11 Mar 2021 19:02:58

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000001

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:23:36
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:03:02
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 19:02:58

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered		
'USA-US130-2020-MRNA-1273-P301000004'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'John'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Sanders'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '100 Medical Center Blvd'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Winston-Salem'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'NC'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '27157'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:37:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered 'US'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 17:07:14
User entered '2'	System	27 Jan 2021 17:38:51
User entered '1'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered		
'USA-US130-2020-MRNA-1273-P301000004'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'John'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Sanders'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '100 Medical Center Blvd'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Winston-Salem'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'NC'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '27157'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 17:37:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered 'US'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 17:07:14
User entered '2'	System	27 Jan 2021 17:38:51
User entered '1'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered '29/Dec/2020 15:36'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:37:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered		
'USA-US130-2020-MRNA-1273-P301000004'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'John'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Sanders'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '100 Medical Center Blvd'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Winston-Salem'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'NC'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '27157'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:37:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered 'US'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 17:07:14
User entered '2'	System	27 Jan 2021 17:38:51
User entered '1'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 17:16:56
User entered '27/Jan/2021 17:38'	System	27 Jan 2021 17:38:51

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:07:24
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 17:16:56
User entered 'I'	(b) (4), (b) (6)	27 Jan 2021 17:38:51

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered		
'USA-US130-2020-MRNA-1273-P301000004'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Yes (Y)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'No (N)'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'John'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Sanders'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '100 Medical Center Blvd'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'Winston-Salem'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered 'NC'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Jan 2021 13:56:29
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 15:36:44
User entered '27157'	System	29 Dec 2020 15:33:27

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 17:37:52
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:56:29
User entered 'US'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Mar 2021 17:07:14
User entered '2'	System	27 Jan 2021 17:38:51
User entered '1'	System	29 Dec 2020 15:37:17

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:43:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
User entered '11/Mar/2021 12:06'	(b) (4) System	11 Mar 2021 17:07:14

US3762161

Folder: SAE USA-US130-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:43:36

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.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:24:24
User signature succeeded.	John Sanders (b) (4)	12 Apr 2021 18:34:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 17:07:24
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 17:07:14