

US3862119 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:05:43

All time stamps listed in this document are displayed in GMT

US3862119

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:23:52

Generated On: 10 Jun 2021 10:05:43

Participant ID

US3862119

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

US3862119

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3862119

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Were any significant conditions reported?

Yes ☒

No ☐

US3862119

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	23 FEB 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3862119

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

Condition	HYPERTENSION
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)	_____

US3862119

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862119

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

Condition	HYPERCHOLESTEROLEMIA
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)	

US3862119

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

Condition	CORONARY ARTERY BYPASS GRAFT SURGERY
Start date (dd MMM yyyy)	23 FEB 2015
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)	23 FEB 2015
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2015
Start Year (derived)	2015
Stop Month and Year (derived)	FEB 2015
Stop Year (derived)	2015

US3862119

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 15:56:48

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:18
Height (<i>xxx.x</i>)	72 in
Weight (<i>xxx.x</i>)	163.6 lb
BMI (<i>xxx.x</i>)	22.23454 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862119

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3862119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3862119

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

What was the participant's randomization number? 189690

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 ☒

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Height	ND - Not Done
Weight	ND - Not Done

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	09:18 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 09:18
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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)	3 SEP 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 11:45
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3862119

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 3 SEP 2020

What was the treatment time? (00:00-23:59) 11:11 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 11:11

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

US3862119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

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

Collection date (dd MMM yyyy)	3 SEP 2020
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Collection time (00:00-23:59)	09:59 (24 HR)
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Collection date and time (derived)	3 SEP 2020 09:59
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US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:42	3 SEP 2020 09:42
Nasopharyngeal Swab 2	No		

US3862119

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

03 SEP 2020 11:51

PC Open Date & Time

03 SEP 2020 11:31

PC Close Date & Time

03 SEP 2020 14:01

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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 96.1 °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	03 SEP 2020 20:07
PC Open Date & Time	03 SEP 2020 14:56
PC Close Date & Time	04 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

95.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:18

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

05 SEP 2020 18:39

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

95.7 °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 18:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

07 SEP 2020 19:30

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

96.8 °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

08 SEP 2020 20:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

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

09 SEP 2020 21:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

03 SEP 2020 11:52

PC Open Date & Time

03 SEP 2020 11:31

PC Close Date & Time

03 SEP 2020 14:01

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

5

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

03 SEP 2020 20:09

PC Open Date & Time

03 SEP 2020 14:56

PC Close Date & Time

04 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

4

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

05 SEP 2020 18:39

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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)

4

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

06 SEP 2020 18:52

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 19:30

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 20:32

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 21:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 11:52
PC Open Date & Time	03 SEP 2020 11:31
PC Close Date & Time	03 SEP 2020 14:01

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 20:09
PC Open Date & Time	03 SEP 2020 14:56
PC Close Date & Time	04 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

		Yes <input type="checkbox"/>
PC Time stamp	04 SEP 2020 20:19	
PC Open Date & Time	04 SEP 2020 12:00	
PC Close Date & Time	05 SEP 2020 11:59	

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 18:40
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:53
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:31
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

58 of 2968

EAB) (1725)

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:33
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

60 of 2968

EAB) (1725)

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:06
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3862119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

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)	1 OCT 2020
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 08:56
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	089 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

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)	1 OCT 2020
Time of assessment (00:00-23:59)	11:45 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 11:45
Temperature (xxx.x)	097.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	089 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3862119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

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) 1 OCT 2020

What was the treatment time? (00:00-23:59) 10:17 (24 HR)

Treatment Date and Time (derived) 1 OCT 2020 10:17

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

US3862119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	09:23 (24 HR)
Collection date and time (derived)	1 OCT 2020 09:23

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	09:20	1 OCT 2020 09:20

US3862119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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):

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

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

PC Time Stamp 01 OCT 2020 10:56

PC Open Date & Time 01 OCT 2020 10:37

PC Close Date & Time 01 OCT 2020 13:07

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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 96.0 °F

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

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

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

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

PC Time Stamp 01 OCT 2020 19:54

PC Open Date & Time 01 OCT 2020 14:02

PC Close Date & Time 02 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	02 OCT 2020 20:12
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	03 OCT 2020 20:17
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 20:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

06 OCT 2020 09:58

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

06 OCT 2020 21:15

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 OCT 2020 16:39

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

01 OCT 2020 10:57

PC Open Date & Time

01 OCT 2020 10:37

PC Close Date & Time

01 OCT 2020 13:07

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

01 OCT 2020 19:54

PC Open Date & Time

01 OCT 2020 14:02

PC Close Date & Time

02 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

50

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 20:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

30

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 20:17

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

04 OCT 2020 20:04

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

9

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 - **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 09:59

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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 21:15

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

07 OCT 2020 16:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 10:57
PC Open Date & Time	01 OCT 2020 10:37
PC Close Date & Time	01 OCT 2020 13:07

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 19:54
PC Open Date & Time	01 OCT 2020 14:02
PC Close Date & Time	02 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

96 of 2968

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 20:13
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:17
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2968

EAB) (1725)

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

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 ☒

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:16
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

106 of 2968

EAB) (1725)

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 16:40
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3862119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:47

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 08:56
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3862119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	08:46 (24 HR)
Collection date and time (derived)	30 OCT 2020 08:46

US3862119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:44:48

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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°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"/>

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
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Patient Cloud Close Date & Time	09 DEC 2020 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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	False <input type="checkbox"/>
New loss of taste	False <input type="checkbox"/>
New loss of smell	False <input type="checkbox"/>
Sore throat	False <input type="checkbox"/>
Congestion	False <input type="checkbox"/>
Runny nose	False <input type="checkbox"/>
Nausea	False <input type="checkbox"/>
Vomiting	False <input type="checkbox"/>
Diarrhea	False <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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 DEC 2020 13:33:09
Patient Cloud Open Date & Time	26 DEC 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
135 of 2968	

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 08:14:30
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 14:45:50

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 05:21:57

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 09:59:47

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

01 FEB 2021 13:16:49

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

09 FEB 2021 09:17:09

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

21 FEB 2021 15:02:26

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

28 FEB 2021 13:58:43

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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	09 MAR 2021 11:06:39
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

28 MAR 2021 16:24:23

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 11:14:44

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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	10 APR 2021 08:21:35
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 13:21:12

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 03:59:02

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Patient Cloud Open Date & Time	25 DEC 2021 00:01
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Patient Cloud Close Date & Time	29 DEC 2021 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 <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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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°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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 663
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

Patient Cloud Open Date & Time	20 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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"/>

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3862119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:05:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:58:56

US3862119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:30:16

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:30:16

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

Visit date (dd MMM yyyy)	31 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 MAR 2021
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 09:42
Temperature (xxx.x)	097.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 MAR 2021

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

US3862119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

Collection date (dd MMM yyyy)	31 MAR 2021
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Collection time (00:00-23:59)	09:54 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	31 MAR 2021 09:54
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US3862119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Apr 2021 16:49:12

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3862119

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Apr 2021 16:49:12

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862119

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862119

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☐

US3862119

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

Visit date (dd MMM yyyy)	25 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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US3862119

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Date of updated informed consent (dd MMM yyyy) 25 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) 25 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 _____

US3862119

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

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

Collection date (dd MMM yyyy)	25 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 JAN 2021 09:27
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US3862119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	09:26
Collection Date and Time (derived)	25 JAN 2021 09:26

US3862119

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	3 SEP 2020
Start time (00:00-23:59)	22:00 (24 HR)
AE start date and time (derived)	3 SEP 2020 22:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	3 SEP 2020
End time (00:00-23:59)	23:59 (24 HR)
AE End Date and Time (derived)	3 SEP 2020 23:59
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)

341 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

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)	0
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	GUM INFECTION RIGHT UPPER QUADRANT GUM AREA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

347 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

AEID	USA-US121-2021-MRNA-1273-P30 1000002
Adverse event	WORSENING OF PAROXYSMAL ATRIAL FIBRILLATION
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)	01 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	23 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	349 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

MRNA-1273-P301

SUBJECT: US3862119

25 FEB 2021 8:30

69 YEARS OLD CAUCASIAN

MALE

MEDICAL HISTORY: CAD, S/P
CABG, ATRIAL FIBRILLATION,
HYPERTENSION,
HYPERCHOLESTEROLEMIA,
SEASONAL ALLERGIES
MEDICATION: ATORVASTATIN,
LOSARTAN, XARELTO,
CETIRIZINE

AMENDMENT 6 PROTOCOL
UNBLINDED: 25 JAN 2021
RANDOMIZED MRNA 1273
FIRST DOSE: 03 SEP 2020
SECOND DOSE: 01 OCT 2020
1.EVALUATED BY
ELECTROPHYSIOLOGIST
CARDIOLOGIST ON 08 FEB 2021
FOR EXISTING MILD
INTERMITTENT
LIGHTHEADEDNESS
(PREVIOUSLY REPORTED AS
AN ADVERSE EVENT.
INITIALLY EVALUATED BY
CURRENT CARDIOLOGIST FOR
SAME SYMPTOM ON 18 JAN
2021. HAD HOLTER
MONITORING ON THE SAME
DAY. HAD ECHOCARDIOGRAM
AND CARDIAC MRI ON 20 JAN
2021 WHICH SHOWED
ISCHEMIC CARDIOMYOPATHY

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

(PREVIOUSLY REPORTED AS
AN ADVERSE EVENT).
ELECTROPHYSIOLOGIST
CARDIOLOGIST
RECOMMENDED
IMPLANTATION OF DUAL
CHAMBER IMPLANTABLE
CARDIOVERTER
DEFIBRILLATOR (ICD) FOR
VENTRICULAR ARRHYTHMIA.
2. ADMITTED IN METHODIST
HOSPITAL ON 23 FEB 2021 FOR
ICD IMPLANTATION
PROCEDURE, DISCHARGED
HOME IN STABLE CONDITION
ON 24 FEB 2021.
3.DISCHARGE MEDICATIONS:
MINOCYCLINE 100 MG 1
CAPSULE PO BID X 5 DAYS
(PROPHYLAXIS FOR ICD
IMPLANTATION SITE
INFECTION) AND
HYDROCODONE/ACETAMINOP
HEN 5MG/325MG 1 TABLET PO
EVERY 6 HOURS AS NEEDED
FOR PAIN ON IMPLANTATION
SITE.
4.25 FEB 2021:DENIED ANY
CHEST PAIN, PALPITATION
AND SHORTNESS OF BREATH,
FEVER AND CHILLS. HAD ONE
EPISODE OF MILD
LIGHTHEADEDNESS
YESTERDAY EVENING WHICH
RESOLVED SPONTANEOUSLY.
CURRENTLY, HAVING
INTERMITTENT MODERATE

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

PAIN IN LEFT UPPER
ANTERIOR CHEST AREA
(IMPLANTATION SITE),
AWAITING
HYDROCODONE/ACETAMINOP
HEN FROM PHARMACY.
5.FOLLOW-UP APPOINTMENT
WITH ELECTROPHYSIOLOGIST
CARDIOLOGIST WILL BE ON 04
MARCH 2021.
ABOVE INFORMATION
DISCUSSED WITH PRINCIPAL
INVESTIGATOR. VENTRICULAR
ARRYTHMIA REPORTED AS A
SERIOUS ADVERSE EVENT.
SUBJECT WILL BE CLOSELY
MONITORED. MEDICAL
RECORDS WILL BE
REQUESTED.
ADDENDUM: 19 FEB 2021 COVID
19 QUALITATIVE PCR TEST-
NOT DETECTED

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

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

AEID

Adverse event

PAIN ON LEFT UPPER
ANTERIOR CHEST AREA (ICD
IMPLANTATION SITE)

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)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒
No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious?

Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

354 of 2968

EAB) (1725)

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	HEMATURIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

356 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	DIARRHEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

AEID

Adverse event

PREMATURE VENTRICULAR
CONTRACTION

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)

18 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

360 of 2968

EAB) (1725)

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

364 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	URETHRAL STONE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

AEID

Adverse event

UNDETERMINED UROTHELIAL
FINDINGS

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)

01 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

368 of 2968

EAB) (1725)

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

AEID	
Adverse event	LOW GRADE FEVER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 FEB 2021
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

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:23:53

Generated On: 10 Jun 2021 10:05:43

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

Yes ☒

No ☐

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

373 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication XARELTO

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication IMODIUM

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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)		3 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 3 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication PAIN ON INJECTION SITE POST
VACCINATION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	1 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
TOOTHACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication CETRIZINE HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

391 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	INFLUENZA
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

393 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication GUM INFECTION RIGHT UPPER
QUADRANT GUM AREA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

395 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	31 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ORA-GEL

Prophylaxis Yes ☐
No ☒

Indication GUM INFECTION RIGHT UPPER
QUADRANT GUM AREA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR
THROMBOEMBOLIC EVENT

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

399 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication IMODIUM

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

401 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication PEPTOBISMOL

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

403 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

405 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	04 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication MINOCYCLINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR ICD
IMPLANTATION SITE
INFECTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

407 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication TRAMADOL HCL

Prophylaxis Yes ☐
No ☒

Indication PAIN ON LEFT UPPER
ANTERIOR CHEST AREA (ICD
IMPLANTATION SITE)

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

EVERY 6 HRS AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

409 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication IMPLANTATION OF DUAL
CHAMBER ICD

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

411 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication IMPLANTATION OF DUAL
CHAMBER ICD

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

413 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication ETOMIDATE

Prophylaxis Yes ☐
No ☒

Indication IMPLANTATION OF DUAL
CHAMBER ICD

Dose per administration 6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

415 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication PAROXYMAL ATRIAL
FIBRILATION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

417 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication DYSURIA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

419 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication URETHRAL STONE

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)

421 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication DUAL CHAMBER
DEFIBRILATOR IMPLANTATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

423 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	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)	23 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF PAROXYSMAL
ATRIAL FIBRILLATION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE A DAY AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

425 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	01 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)		04 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LOW GRADE FEVER

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

427 of 2968

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 23 Apr 2021 14:01:08

Generated On: 10 Jun 2021 10:05:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:23:54

Generated On: 10 Jun 2021 10:05:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 18:35:23

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 NOV 2020	COLONOSCOPY	Other	ROUTINE SCREENING
20 JAN 2021	CARDIAC MRI	Adverse Event	
18 JAN 2021	HOLTER MONITOR	Adverse Event	
23 FEB 2021	IMPLANTATION OF DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)	Adverse Event	
01 APR 2021	CT OF THE ABDOMEN	Adverse Event	

US3862119

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:05:43

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

US3862119

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:05:43

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 ☐

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/FEB/2021 15:09
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

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/FEB/2021 15:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	15/MAR/2021 10:58
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

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	24/MAR/2021 18:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/MAR/2021 08:47
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

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	06/APR/2021 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

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Apr 2021 14:01:09

Generated On: 10 Jun 2021 10:05:43

SAEID	USA-US121-2021-MRNA-1273-P301000002
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/APR/2021 12:18
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3862119 (Prod: Baylor College of Medicine)

US3862119

Form: Participant Creation

Generated On: 10 Jun 2021 10:05:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'US3862119'	RWS_ENDPOINT	03 Sep 2020 14:39:59
	ENDPOINT (b) (4)	
	(b) (4)	

US3862119

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	03 Sep 2020 16:14:04
	(b) (4)	

US3862119

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '03 SEP 2020'	RWS_ENDPOINT	03 Sep 2020 14:40:00
	ENDPOINT (b) (4)	
	(b) (4)	

US3862119

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Chanei Henry (b) (4)	03 Sep 2020 16:14:04
	(b) (4)	

US3862119

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'SCRN'	System	03 Sep 2020 16:14:04

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered (b) (6) 1952'	RWS_ENDPOINT	03 Sep 2020 14:40:01
	ENDPOINT (b) (4)	
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '68'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'YEARS'	System	03 Sep 2020 16:15:02

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '68'	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Male (M)'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'I'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:05:43

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	03 Sep 2020 16:15:02
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '3 Sep 2020'	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Sep 2020'	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2020'	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Amendment 3 (3)'	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	03 Sep 2020 16:13:31
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	RWS_ENDPOINT	03 Sep 2020 14:40:00
	ENDPOINT (b) (4)	
	(b) (4)	

US3862119

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:05:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '1'	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	03 Sep 2020 16:13:19
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:05:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:15:15
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLG: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:27:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:27:52
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:26:55
User entered 'coronary artery disease'	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '23 Feb 2015'	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:26:51
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Feb 2015'	System	03 Sep 2020 20:26:51

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	03 Sep 2020 20:26:51

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:26:51

US3862119

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:26:51

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:14:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 14:14:13
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 00:02:53
Coding entries removed.	Thea Marie Cordero	26 Mar 2021 00:01:34
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	26 Mar 2021 00:01:34
	(b) (4)	
User entered 'PAROXYSMAL ATRIAL FIBRILLATION' reason for change: New Information	Thea Marie Cordero	26 Mar 2021 00:01:34
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:28:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:28:42
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:27:56
User entered 'atrial fibrillation'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'un UNK 2015'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:14
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2015'	System	03 Sep 2020 20:27:14

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	03 Sep 2020 20:27:14

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:27:14

US3862119

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:27:14

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
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)	03 Sep 2020 20:28:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:28:43
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 20:27:58
User entered 'hypertension'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'un UNK 2010'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:27:24
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2010'	System	03 Sep 2020 20:27:24

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2010'	System	03 Sep 2020 20:27:24

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:27:24

US3862119

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	03 Sep 2020 20:27:24

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 16:27:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Oct 2020 16:27:13
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:21:26
User entered 'SEASONAL ALLERGIES'	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'UN UNK 1958'	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	16 Oct 2020 16:21:07
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 1958'	System	16 Oct 2020 16:21:07

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '1958'	System	16 Oct 2020 16:21:07

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	16 Oct 2020 16:21:07

US3862119

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	16 Oct 2020 16:21:07

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:45:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:45:48
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 00:45:02
User entered 'HYPERCHOLESTEROLEMIA'	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'UN UNK 2010'	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:44:50
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2010'	System	24 Mar 2021 00:44:50

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2010'	System	24 Mar 2021 00:44:50

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	24 Mar 2021 00:44:50

US3862119

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	24 Mar 2021 00:44:50

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: 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)	24 Mar 2021 00:47:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:47:49
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 00:47:03
User entered 'CORONARY ARTERY BYPASS GRAFT SURGERY'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '23 Feb 2015'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '23 Feb 2015'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:46:32
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Feb 2015'	System	24 Mar 2021 00:46:32

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	24 Mar 2021 00:46:32

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Feb 2015'	System	24 Mar 2021 00:46:32

US3862119

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	24 Mar 2021 00:46:32

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 13:56:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 13:56:48
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 13:55:43
User entered 'MYOCARDIAL INFARCTION'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'UN UNK 2015'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'UN UNK 2015'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 13:55:38
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2015'	System	26 Mar 2021 13:55:38

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	26 Mar 2021 13:55:38

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2015'	System	26 Mar 2021 13:55:38

US3862119

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	26 Mar 2021 13:55:38

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Ischaemic cardiomyopathy, LLT: Ischemic cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:21:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 14:21:46
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 14:05:07
User entered 'ISCHEMIC CARDIOMYOPATHY'	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'UN UNK 2015'	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 14:04:57
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2015'	System	26 Mar 2021 14:04:57

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	26 Mar 2021 14:04:57

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	26 Mar 2021 14:04:57

US3862119

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	26 Mar 2021 14:04:57

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 17:20:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 17:20:27
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 17:19:49
User entered 'CONGESTIVE HEART FAILURE'	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'UN UNK 2015'	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:49
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 17:19:22
	(b) (4)	

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'Jan 2015'	System	26 Mar 2021 17:19:22

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '2015'	System	26 Mar 2021 17:19:22

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	26 Mar 2021 17:19:22

US3862119

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	26 Mar 2021 17:19:22

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '3 Sep 2020'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '09:18'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '3 Sep 2020 09:18'	System	03 Sep 2020 20:28:03

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '72' in	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	
DataPoint set to visible.	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '163.6' lb	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	
DataPoint set to visible.	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '22.23454'	System	03 Sep 2020 20:28:03
DataPoint set to visible.	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'kg/m2'	System	03 Sep 2020 20:28:03
DataPoint set to visible.	System	03 Sep 2020 16:13:31

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '97.7' F	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Oral (Oral)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '74'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'bpm'	System	03 Sep 2020 20:28:03

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '18'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'breaths/min'	System	03 Sep 2020 20:28:03

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '120'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'mmHg'	System	03 Sep 2020 20:28:03

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '78'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:03
	(b) (4)	

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'mmHg'	System	03 Sep 2020 20:28:03

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53

US3862119

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53

US3862119

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:15:08
	(b) (4)	

US3862119

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '3 Sep 2020'	Carrie Kibler (b) (4)	03 Sep 2020 18:15:08
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

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)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered 'I'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:05:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	03 Sep 2020 20:28:33
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:36

US3862119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:36

US3862119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:36

US3862119

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'VISIT1'	System	03 Sep 2020 18:15:36

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 15:29:36

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '189690'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 15:29:36

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	03 Sep 2020 15:29:36

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

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)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:28:53

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

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)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:28:53

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:28:53

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:28:53

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:28:53

US3862119

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:05:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 18:34:52
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:09:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:09:57

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:08:35
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:12:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:12:04
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:35:59
User entered '72' in	Carrie Kibler (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 17:12:04
	(b) (4)	
User entered '163.6' lb	Carrie Kibler (b) (4)	03 Sep 2020 20:29:28
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:08:35
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:12:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:12:04
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:35:59
User entered '72' in	Carrie Kibler (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:12:04
User entered '163.6' lb	Carrie Kibler (b) (4)	03 Sep 2020 20:29:28
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '09:18'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '3 Sep 2020 09:18'	System	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '97.7' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Oral (Oral)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '74'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'bpm'	System	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '18'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'breaths/min'	System	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '120'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '78'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:08:35
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:12:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:12:04
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:35:59
User entered '72' in	Carrie Kibler (b) (4)	03 Sep 2020 20:29:28

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:05:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:12:04
User entered '163.6' lb	Shetel Anassi (b) (4)	03 Sep 2020 20:29:28
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '11:45'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '3 Sep 2020 11:45'	System	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '97.4' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '60'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'bpm'	System	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '12'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'breaths/min'	System	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '128'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '64'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	03 Sep 2020 20:30:03

US3862119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:43

US3862119

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:43

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

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)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50
	(b) (4)	

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '11:11'	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '3 Sep 2020 11:11'	System	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) Chanei Henry (b) (4)	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'ONCE'	System	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 16:13:50

US3862119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:19

US3862119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:19

US3862119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '09:59'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:19

US3862119

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '3 Sep 2020 09:59'	System	03 Sep 2020 20:30:19

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '3 Sep 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:33

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:33

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:33

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '09:42'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:33

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '3 Sep 2020 09:42'	System	03 Sep 2020 20:30:33

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:38

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:38

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 20:30:38

US3862119

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered empty.	System	03 Sep 2020 20:30:38

US3862119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	03 Sep 2020 18:15:49

US3862119

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	03 Sep 2020 18:15:49

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0d4b2f8c-126f-4c78-a1ab-6f4ba395468e'	System	03 Sep 2020 16:51:29
User entered 'Yes (Y)'	System	03 Sep 2020 16:51:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:13', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0d4b2f8c-126f-4c78-a1ab-6f4ba395468e' User entered '97.4'	System	03 Sep 2020 16:51:29
	System	03 Sep 2020 16:51:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0d4b2f8c-126f-4c78-a1ab-6f4ba395468e'	System	03 Sep 2020 16:51:29
User entered 'No (N)'	System	03 Sep 2020 16:51:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:25', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0d4b2f8c-126f-4c78-a1ab-6f4ba395468e'	System	03 Sep 2020 16:51:29
User entered '03 Sep 2020 11:51'	System	03 Sep 2020 16:51:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 11:31'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:07:12', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9264b2ef-4532-4d3d-bbee-0488d17c0e52'	System	04 Sep 2020 01:07:31
User entered 'Yes (Y)'	System	04 Sep 2020 01:07:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:07:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9264b2ef-4532-4d3d-bbee-0488d17c0e52'	System	04 Sep 2020 01:07:31
User entered '96.1'	System	04 Sep 2020 01:07:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:07:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9264b2ef-4532-4d3d-bbee-0488d17c0e52'	System	04 Sep 2020 01:07:31
User entered 'No (N)'	System	04 Sep 2020 01:07:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:07:28', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9264b2ef-4532-4d3d-bbee-0488d17c0e52'	System	04 Sep 2020 01:07:31
User entered '03 Sep 2020 20:07'	System	04 Sep 2020 01:07:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:56'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 2'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:17:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '619e6637-cb2b-4a3e-9224-e38af5b27247'	System	05 Sep 2020 01:18:08
User entered 'Yes (Y)'	System	05 Sep 2020 01:18:08

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:17:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '619e6637-cb2b-4a3e-9224-e38af5b27247'	System	05 Sep 2020 01:18:08
User entered '95.7'	System	05 Sep 2020 01:18:08

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:17:59', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '619e6637-cb2b-4a3e-9224-e38af5b27247'	System	05 Sep 2020 01:18:08
User entered 'No (N)'	System	05 Sep 2020 01:18:08

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:18:04', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '619e6637-cb2b-4a3e-9224-e38af5b27247'	System	05 Sep 2020 01:18:08
User entered '04 Sep 2020 20:18'	System	05 Sep 2020 01:18:08

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 3'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:06', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '82bcacc8-93be-4f6e-bec0-08cdf7304ac5'	System	05 Sep 2020 23:39:31
User entered 'Yes (Y)'	System	05 Sep 2020 23:39:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '82bcacc8-93be-4f6e-bec0-08cdf7304ac5'	System	05 Sep 2020 23:39:31
User entered '97.2'	System	05 Sep 2020 23:39:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '82bcacc8-93be-4f6e-bec0-08cdf7304ac5'	System	05 Sep 2020 23:39:31
User entered 'No (N)'	System	05 Sep 2020 23:39:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '82bcacc8-93be-4f6e-bec0-08cdf7304ac5'	System	05 Sep 2020 23:39:31
User entered '05 Sep 2020 18:39'	System	05 Sep 2020 23:39:31

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 4'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:05', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ee97c528-978a-411f-925d-607da2550c11'	System	06 Sep 2020 23:52:29
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:52:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ee97c528-978a-411f-925d-607da2550c11' User entered '95.7'	System	06 Sep 2020 23:52:29
	System	06 Sep 2020 23:52:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ee97c528-978a-411f-925d-607da2550c11'	System	06 Sep 2020 23:52:29
User entered 'No (N)'	System	06 Sep 2020 23:52:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ee97c528-978a-411f-925d-607da2550c11'	System	06 Sep 2020 23:52:29
User entered '06 Sep 2020 18:52'	System	06 Sep 2020 23:52:29

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 5'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:07', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1a62737b-6418-4a70-977b-1deb442c5a17'	System	08 Sep 2020 00:30:26
User entered 'Yes (Y)'	System	08 Sep 2020 00:30:26

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:16', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1a62737b-6418-4a70-977b-1deb442c5a17'	System	08 Sep 2020 00:30:26
User entered '97.4'	System	08 Sep 2020 00:30:26

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1a62737b-6418-4a70-977b-1deb442c5a17'	System	08 Sep 2020 00:30:26
User entered 'No (N)'	System	08 Sep 2020 00:30:26

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1a62737b-6418-4a70-977b-1deb442c5a17'	System	08 Sep 2020 00:30:26
User entered '07 Sep 2020 19:30'	System	08 Sep 2020 00:30:26

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 6'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '60040953-5b45-4be3-81df-ec7c997ebb8b'	System	09 Sep 2020 01:32:20
User entered 'Yes (Y)'	System	09 Sep 2020 01:32:20

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '60040953-5b45-4be3-81df-ec7c997ebb8b' User entered '96.8'	System	09 Sep 2020 01:32:20
	System	09 Sep 2020 01:32:20

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:11', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '60040953-5b45-4be3-81df-ec7c997ebb8b'	System	09 Sep 2020 01:32:20
User entered 'No (N)'	System	09 Sep 2020 01:32:20

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:14', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '60040953-5b45-4be3-81df-ec7c997ebb8b'	System	09 Sep 2020 01:32:20
User entered '08 Sep 2020 20:32'	System	09 Sep 2020 01:32:20

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 7'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:05:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6a7f3309-1a61-4783-9ce3-21a9ac2708d8'	System	10 Sep 2020 02:05:52
User entered 'Yes (Y)'	System	10 Sep 2020 02:05:52

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:05:40', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6a7f3309-1a61-4783-9ce3-21a9ac2708d8'	System	10 Sep 2020 02:05:52
User entered '96.3'	System	10 Sep 2020 02:05:52

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:05:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6a7f3309-1a61-4783-9ce3-21a9ac2708d8'	System	10 Sep 2020 02:05:52
User entered 'No (N)'	System	10 Sep 2020 02:05:52

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:05:47', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6a7f3309-1a61-4783-9ce3-21a9ac2708d8'	System	10 Sep 2020 02:05:52
User entered '09 Sep 2020 21:05'	System	10 Sep 2020 02:05:52

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T11:51:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'be84e676-6b7e-4aba-ba3d-15a534685b9e'	System	03 Sep 2020 16:52:08
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:52:08

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:49', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'be84e676-6b7e-4aba-ba3d-15a534685b9e'	System	03 Sep 2020 16:52:08
User entered 'No (N)'	System	03 Sep 2020 16:52:08

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:51:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'be84e676-6b7e-4aba-ba3d-15a534685b9e'	System	03 Sep 2020 16:52:08
User entered 'No (N)'	System	03 Sep 2020 16:52:08

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T11:51:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'be84e676-6b7e-4aba-ba3d-15a534685b9e'	System	03 Sep 2020 16:52:08
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:52:08

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:04', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'be84e676-6b7e-4aba-ba3d-15a534685b9e'	System	03 Sep 2020 16:52:08
User entered '03 Sep 2020 11:52'	System	03 Sep 2020 16:52:08

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 11:31'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:07:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered 'None (1)'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T20:07:47', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered 'No (N)'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T20:07:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered 'Yes (Y)'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:03', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered '5'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:07', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered 'None (1)'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T20:09:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '007171ac-7a9b-4966-86fe-8b78707d6fd5'	System	04 Sep 2020 01:09:18
User entered '03 Sep 2020 20:09'	System	04 Sep 2020 01:09:18

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:56'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 2'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:18:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:18:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered 'No (N)'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:18:21', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered 'Yes (Y)'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe9d)', Time: '2020-09-04T20:18:59', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered '10'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:19:11', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered 'None (1)'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2cfca87c-aea3-486d-b86d-7f20db36c440'	System	05 Sep 2020 01:19:21
User entered '04 Sep 2020 20:19'	System	05 Sep 2020 01:19:21

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 3'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb'	System	05 Sep 2020 23:40:03
User entered 'None (1)'	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:39:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb'	System	05 Sep 2020 23:40:03
User entered 'No (N)'	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe9d)', Time: '2020-09-05T18:39:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb'	System	05 Sep 2020 23:40:03
User entered 'Yes (Y)'	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb'	System	05 Sep 2020 23:40:03
User entered '4'	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:39:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb'	System	05 Sep 2020 23:40:03
User entered 'None (1)'	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:39:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'df32ebc2-8fdf-4857-ab43-aaf3b94d25eb' User entered '05 Sep 2020 18:39'	System	05 Sep 2020 23:40:03
	System	05 Sep 2020 23:40:03

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 4'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:37', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered 'No (N)'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:52:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered 'Yes (Y)'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered '4'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered 'None (1)'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:52:54', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd885be59-0ec3-415f-a1c6-a43dddbef0b6'	System	06 Sep 2020 23:52:57
User entered '06 Sep 2020 18:52'	System	06 Sep 2020 23:52:57

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 5'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'de922253-e580-421a-ad7a-b9e85a4bd59b'	System	08 Sep 2020 00:30:49
User entered 'None (1)'	System	08 Sep 2020 00:30:49

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:35', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'de922253-e580-421a-ad7a-b9e85a4bd59b'	System	08 Sep 2020 00:30:49
User entered 'No (N)'	System	08 Sep 2020 00:30:49

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'de922253-e580-421a-ad7a-b9e85a4bd59b'	System	08 Sep 2020 00:30:49
User entered 'No (N)'	System	08 Sep 2020 00:30:49

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'de922253-e580-421a-ad7a-b9e85a4bd59b'	System	08 Sep 2020 00:30:49
User entered 'None (1)'	System	08 Sep 2020 00:30:49

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'de922253-e580-421a-ad7a-b9e85a4bd59b'	System	08 Sep 2020 00:30:49
User entered '07 Sep 2020 19:30'	System	08 Sep 2020 00:30:49

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 6'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'bd4bae1e-4f41-4b96-8c7a-eb42fec167ea'	System	09 Sep 2020 01:32:43
User entered 'None (1)'	System	09 Sep 2020 01:32:43

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'bd4bae1e-4f41-4b96-8c7a-eb42fec167ea'	System	09 Sep 2020 01:32:43
User entered 'No (N)'	System	09 Sep 2020 01:32:43

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:29', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'bd4bae1e-4f41-4b96-8c7a-eb42fec167ea'	System	09 Sep 2020 01:32:43
User entered 'No (N)'	System	09 Sep 2020 01:32:43

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'bd4bae1e-4f41-4b96-8c7a-eb42fec167ea'	System	09 Sep 2020 01:32:43
User entered 'None (1)'	System	09 Sep 2020 01:32:43

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:37', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'bd4bae1e-4f41-4b96-8c7a-eb42fec167ea'	System	09 Sep 2020 01:32:43
User entered '08 Sep 2020 20:32'	System	09 Sep 2020 01:32:43

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 7'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:06:13', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6b49f560-b72e-4f20-b8c7-2870cc1860e8'	System	10 Sep 2020 02:06:37
User entered 'None (1)'	System	10 Sep 2020 02:06:37

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:16', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6b49f560-b72e-4f20-b8c7-2870cc1860e8'	System	10 Sep 2020 02:06:37
User entered 'No (N)'	System	10 Sep 2020 02:06:37

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:20', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6b49f560-b72e-4f20-b8c7-2870cc1860e8'	System	10 Sep 2020 02:06:37
User entered 'No (N)'	System	10 Sep 2020 02:06:37

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:06:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6b49f560-b72e-4f20-b8c7-2870cc1860e8'	System	10 Sep 2020 02:06:37
User entered 'None (1)'	System	10 Sep 2020 02:06:37

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:30', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '6b49f560-b72e-4f20-b8c7-2870cc1860e8'	System	10 Sep 2020 02:06:37
User entered '09 Sep 2020 21:06'	System	10 Sep 2020 02:06:37

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:13', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'None (0)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'None (0)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T11:52:30', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'None (0)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:33', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'None (0)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T11:52:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered 'No (N)'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T11:52:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'd0a34f6e-c62a-41e5-b778-b827fab52854'	System	03 Sep 2020 16:52:50
User entered '03 Sep 2020 11:52'	System	03 Sep 2020 16:52:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 11:31'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'No interference with activity (1)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-03T20:09:29', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'None (0)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe9d)', Time: '2020-09-03T20:09:31', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'None (0)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'None (0)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:36', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'None (0)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'None (0)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered 'No (N)'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-03T20:09:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9a6f2f3c-9a21-41de-b470-9d1f490ed9c1'	System	04 Sep 2020 01:09:52
User entered '03 Sep 2020 20:09'	System	04 Sep 2020 01:09:52

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Sep 2020 14:56'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 2'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:29', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:19:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:37', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'None (0)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-04T20:19:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered 'Yes (Y)'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-04T20:19:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '79401d0f-a2f4-49d8-b821-ff09ba54e19a'	System	05 Sep 2020 01:19:58
User entered '04 Sep 2020 20:19'	System	05 Sep 2020 01:19:58

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 3'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:40:05', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:40:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:40:10', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:40:12', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:40:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:40:17', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'None (0)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-05T18:40:22', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered 'No (N)'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-05T18:40:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8275048a-9688-45d9-9ed1-128f4f9aa690'	System	05 Sep 2020 23:40:30
User entered '05 Sep 2020 18:40'	System	05 Sep 2020 23:40:30

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 4'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:52:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:05', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:07', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:09', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:11', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'None (0)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-06T18:53:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered 'No (N)'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-06T18:53:20', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9505b280-7790-45fa-a780-3cf048310217'	System	06 Sep 2020 23:53:23
User entered '06 Sep 2020 18:53'	System	06 Sep 2020 23:53:23

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 5'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:51', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:30:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:30:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:31:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:31:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'None (0)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-07T19:31:04', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered 'No (N)'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-07T19:31:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f42398eb-6da9-425d-8ae3-823ef7861dc2'	System	08 Sep 2020 00:31:12
User entered '07 Sep 2020 19:31'	System	08 Sep 2020 00:31:12

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 6'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b' User entered 'None (0)'	System	09 Sep 2020 01:33:06
	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b'	System	09 Sep 2020 01:33:06
User entered 'None (0)'	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b' User entered 'None (0)'	System	09 Sep 2020 01:33:06
	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:50', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b' User entered 'None (0)'	System	09 Sep 2020 01:33:06
	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b' User entered 'None (0)'	System	09 Sep 2020 01:33:06
	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-08T20:32:54', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b'	System	09 Sep 2020 01:33:06
User entered 'None (0)'	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:32:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b'	System	09 Sep 2020 01:33:06
User entered 'No (N)'	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-08T20:33:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '62bd9098-e91c-4d09-bbce-504e3ecc047b' User entered '08 Sep 2020 20:33'	System	09 Sep 2020 01:33:06
	System	09 Sep 2020 01:33:06

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 7'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:45', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:47', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:49', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'None (0)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-09-09T21:06:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered 'No (N)'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-09-09T21:06:59', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8762ae75-0b97-4f74-922c-3e2d1bba9abf'	System	10 Sep 2020 02:07:05
User entered '09 Sep 2020 21:06'	System	10 Sep 2020 02:07:05

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 16:13:50

US3862119

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:22:51

US3862119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '11 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:22:51
	(b) (4)	

US3862119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:22:51

US3862119

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:22:51
	(b) (4)	

US3862119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	17 Sep 2020 20:30:46
	(b) (4)	

US3862119

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	17 Sep 2020 20:30:46

US3862119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	17 Sep 2020 20:30:59
	(b) (4)	

US3862119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '17 Sep 2020'	(b) (4) Thea Marie Cordero	17 Sep 2020 20:30:59
	(b) (4)	

US3862119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero (b) (4)	17 Sep 2020 20:30:59

US3862119

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Thea Marie Cordero	17 Sep 2020 20:30:59
	(b) (4)	

US3862119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	17 Sep 2020 20:31:04
	(b) (4)	

US3862119

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	17 Sep 2020 20:31:04

US3862119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	24 Sep 2020 22:44:42

US3862119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '24 Sep 2020'	(b) (4) Chanei Henry (b) (4)	24 Sep 2020 22:44:42

US3862119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	24 Sep 2020 22:44:42

US3862119

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Chanei Henry (b) (4)	24 Sep 2020 22:44:42
	(b) (4)	

US3862119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	24 Sep 2020 22:44:47

US3862119

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	24 Sep 2020 22:44:47

US3862119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:24

US3862119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:24

US3862119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Clinic (Clinic)'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:25:24

US3862119

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'VISIT2'	System	01 Oct 2020 15:25:24

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '08:56'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '1 Oct 2020 08:56'	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '097.5' F	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '089'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'bpm'	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'breaths/min'	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '114'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '081'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.'	(b) (4)	
(Site from System).	System	01 Oct 2020 16:13:59
Query 'Data is required. Please provide.' answered by System		01 Oct 2020 16:13:59
data change (Site from System).		
User entered '11:45' reason for change: Data Entry	Trent Davis (b) (4)	01 Oct 2020 16:13:59
Error	(b) (4)	
User opened query 'Data is required. Please provide.'	System	01 Oct 2020 15:26:34
(Site from System).		
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '1 Oct 2020 11:45'	System	01 Oct 2020 16:13:59
User entered empty.	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.'	(b) (4)	
(Site from System).	System	01 Oct 2020 16:13:59
Query 'Data is required. Please provide.' answered by System		01 Oct 2020 16:13:59
data change (Site from System).		
User entered '097.4' F reason for change: Data Entry	Trent Davis (b) (4)	01 Oct 2020 16:13:59
Error	(b) (4)	
User opened query 'Data is required. Please provide.'	System	01 Oct 2020 15:26:34
(Site from System).		
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 16:13:59
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'temporal' reason for change: Data Entry Error	(b) (4)	
	Trent Davis (b) (4)	01 Oct 2020 16:13:59
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	06 Oct 2020 14:08:53
User entered '089' reason for change: Data Entry Error	Trent Davis (b) (4)	01 Oct 2020 16:13:59
	(b) (4)	
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Trent Davis (b) (4)	01 Oct 2020 16:13:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 15:26:34
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'bpm'	System	01 Oct 2020 16:13:59
User entered empty.	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 14:08:55
User entered '016' reason for change: Data Entry Error	Trent Davis (b) (4) (b) (4)	01 Oct 2020 16:13:59
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Trent Davis (b) (4) (b) (4)	01 Oct 2020 16:13:17
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 15:26:34
User entered empty.	Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'breaths/min'	System	01 Oct 2020 16:13:59
User entered empty.	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 16:13:59
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Oct 2020 16:13:59
User entered '114' reason for change: Data Entry Error	Trent Davis (b) (4)	01 Oct 2020 16:13:59
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Oct 2020 15:26:34
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	01 Oct 2020 16:13:59
User entered empty.	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Data is required. Please provide.'	(b) (4)	01 Oct 2020 16:13:59
(Site from System).	System	01 Oct 2020 16:13:59
Query 'Data is required. Please provide.' answered by System		01 Oct 2020 16:13:59
data change (Site from System).		
User entered '081' reason for change: Data Entry	Trent Davis (b) (4)	01 Oct 2020 16:13:59
Error	(b) (4)	
User opened query 'Data is required. Please provide.'	System	01 Oct 2020 15:26:34
(Site from System).		
User entered empty.	Trent Davis (b) (4)	01 Oct 2020 15:26:34
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	01 Oct 2020 16:13:59
User entered empty.	System	01 Oct 2020 15:26:34

US3862119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:42

US3862119

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:42

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

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)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '10:17'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '1 Oct 2020 10:17'	System	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Left Arm (LEFT ARM)'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'ONCE'	System	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:05:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 15:25:13

US3862119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:53

US3862119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:26:53
	(b) (4)	

US3862119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '09:23'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:26:53

US3862119

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '1 Oct 2020 09:23'	System	01 Oct 2020 15:26:53

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '1 Oct 2020'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered empty.	System	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '09:20'	(b) (4) Trent Davis (b) (4) (b) (4)	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '1 Oct 2020 09:20'	System	01 Oct 2020 15:31:54

US3862119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:33

US3862119

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	08 Oct 2020 22:06:33

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	System	01 Oct 2020 15:56:49
User entered 'Yes (Y)'	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	System	01 Oct 2020 15:56:49
User entered '97.4'	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	System	01 Oct 2020 15:56:49
User entered 'Yes (Y)'	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	System	01 Oct 2020 15:56:49
User entered '0'	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med added' (Site from System).	(b) (4)	13 Oct 2020 17:42:18
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Chanei Henry (b) (4)	08 Oct 2020 22:11:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	(b) (4)	
User entered '1'	System	01 Oct 2020 15:56:49
	System	01 Oct 2020 15:56:49
	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ade8f619-a0ea-423e-ae84-994dc63913b3'	System	01 Oct 2020 15:56:49
User entered '01 Oct 2020 10:56'	System	01 Oct 2020 15:56:49

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 10:37'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 13:07'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:53:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	System	02 Oct 2020 00:54:03
User entered 'Yes (Y)'	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:53:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	System	02 Oct 2020 00:54:03
User entered '96.0'	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:53:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	System	02 Oct 2020 00:54:03
User entered 'Yes (Y)'	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Con med added' (Site from System).	(b) (4)	13 Oct 2020 17:42:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Chanei Henry (b) (4)	08 Oct 2020 22:12:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:53:56', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	(b) (4)	
User entered '1'	System	02 Oct 2020 00:54:03
	System	02 Oct 2020 00:54:03
	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:53:56', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	System	02 Oct 2020 00:54:03
User entered '0'	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '253b21f2-4207-4cf3-a44c-abe46d6a8c49'	System	02 Oct 2020 00:54:03
User entered '01 Oct 2020 19:54'	System	02 Oct 2020 00:54:03

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 14:02'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 2'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:11:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e'	System	03 Oct 2020 01:12:18
User entered 'Yes (Y)'	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:11:56', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e' User entered '97.6'	System	03 Oct 2020 01:12:18
	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e'	System	03 Oct 2020 01:12:18
User entered 'Yes (Y)'	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e'	System	03 Oct 2020 01:12:18
User entered '0'	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med recorded' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 17:23:25
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Chanei Henry (b) (4)	08 Oct 2020 22:13:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e'	(b) (4)	
User entered '1'	System	03 Oct 2020 01:12:18
	System	03 Oct 2020 01:12:18
	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:11', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '021c6329-079d-4d73-813c-52d17c59d88e'	System	03 Oct 2020 01:12:18
User entered '02 Oct 2020 20:12'	System	03 Oct 2020 01:12:18

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 3'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:16:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	System	04 Oct 2020 01:17:04
User entered 'Yes (Y)'	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:16:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	System	04 Oct 2020 01:17:04
User entered '97.6'	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:16:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	System	04 Oct 2020 01:17:04
User entered 'Yes (Y)'	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'con med recorded' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 17:24:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Chanei Henry (b) (4)	08 Oct 2020 22:13:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:16:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	(b) (4)	
User entered '1'	System	04 Oct 2020 01:17:04
	System	04 Oct 2020 01:17:04
	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:16:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	System	04 Oct 2020 01:17:04
User entered '0'	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'fa15f4fe-cad7-4d34-b046-f964a7c7216e'	System	04 Oct 2020 01:17:04
User entered '03 Oct 2020 20:17'	System	04 Oct 2020 01:17:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 4'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:03:56', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3a9538e6-fbeb-4734-ae3d-72cc7b8f9e8b'	System	05 Oct 2020 01:04:12
User entered 'Yes (Y)'	System	05 Oct 2020 01:04:12

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3a9538e6-fbeb-4734-ae3d-72cc7b8f9e8b'	System	05 Oct 2020 01:04:12
User entered '97.0'	System	05 Oct 2020 01:04:12

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:06', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3a9538e6-fbeb-4734-ae3d-72cc7b8f9e8b'	System	05 Oct 2020 01:04:12
User entered 'No (N)'	System	05 Oct 2020 01:04:12

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:09', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3a9538e6-fbeb-4734-ae3d-72cc7b8f9e8b'	System	05 Oct 2020 01:04:12
User entered '04 Oct 2020 20:04'	System	05 Oct 2020 01:04:12

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 5'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:58:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ff83985b-c36d-4a35-9aba-51321d1a3be8'	System	06 Oct 2020 14:59:04
User entered 'Yes (Y)'	System	06 Oct 2020 14:59:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:58:51', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ff83985b-c36d-4a35-9aba-51321d1a3be8'	System	06 Oct 2020 14:59:04
User entered '97.2'	System	06 Oct 2020 14:59:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:58:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ff83985b-c36d-4a35-9aba-51321d1a3be8'	System	06 Oct 2020 14:59:04
User entered 'No (N)'	System	06 Oct 2020 14:59:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:58:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ff83985b-c36d-4a35-9aba-51321d1a3be8'	System	06 Oct 2020 14:59:04
User entered '06 Oct 2020 09:58'	System	06 Oct 2020 14:59:04

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 6'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:11', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e18efe6c-717a-491d-8d31-05f5906a41a4'	System	07 Oct 2020 02:15:31
User entered 'Yes (Y)'	System	07 Oct 2020 02:15:31

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T21:15:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e18efe6c-717a-491d-8d31-05f5906a41a4'	System	07 Oct 2020 02:15:31
User entered '97.2'	System	07 Oct 2020 02:15:31

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T21:15:21', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e18efe6c-717a-491d-8d31-05f5906a41a4'	System	07 Oct 2020 02:15:31
User entered 'No (N)'	System	07 Oct 2020 02:15:31

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e18efe6c-717a-491d-8d31-05f5906a41a4'	System	07 Oct 2020 02:15:31
User entered '06 Oct 2020 21:15'	System	07 Oct 2020 02:15:31

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 7'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:39:31', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '50f234f9-44a0-402c-a483-ee75a5d1ec72'	System	07 Oct 2020 21:39:53
User entered 'Yes (Y)'	System	07 Oct 2020 21:39:53

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:39:40', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '50f234f9-44a0-402c-a483-ee75a5d1ec72' User entered '97.3'	System	07 Oct 2020 21:39:53
	System	07 Oct 2020 21:39:53

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:39:45', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '50f234f9-44a0-402c-a483-ee75a5d1ec72'	System	07 Oct 2020 21:39:53
User entered 'No (N)'	System	07 Oct 2020 21:39:53

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:39:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '50f234f9-44a0-402c-a483-ee75a5d1ec72'	System	07 Oct 2020 21:39:53
User entered '07 Oct 2020 16:39'	System	07 Oct 2020 21:39:53

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '451bace1-e397-47c4-8712-29fd48c2580f'	System	01 Oct 2020 15:57:11
User entered 'None (1)'	System	01 Oct 2020 15:57:11

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:56', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '451bace1-e397-47c4-8712-29fd48c2580f'	System	01 Oct 2020 15:57:11
User entered 'No (N)'	System	01 Oct 2020 15:57:11

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:56:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '451bace1-e397-47c4-8712-29fd48c2580f'	System	01 Oct 2020 15:57:11
User entered 'No (N)'	System	01 Oct 2020 15:57:11

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:05', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '451bace1-e397-47c4-8712-29fd48c2580f'	System	01 Oct 2020 15:57:11
User entered 'None (1)'	System	01 Oct 2020 15:57:11

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:08', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '451bace1-e397-47c4-8712-29fd48c2580f' User entered '01 Oct 2020 10:57'	System	01 Oct 2020 15:57:11
	System	01 Oct 2020 15:57:11

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 10:37'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 13:07'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:16', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3f4a1e8b-6595-4ff5-ad95-6557de26a179'	System	02 Oct 2020 00:54:34
User entered 'None (1)'	System	02 Oct 2020 00:54:34

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3f4a1e8b-6595-4ff5-ad95-6557de26a179'	System	02 Oct 2020 00:54:34
User entered 'No (N)'	System	02 Oct 2020 00:54:34

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:21', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3f4a1e8b-6595-4ff5-ad95-6557de26a179'	System	02 Oct 2020 00:54:34
User entered 'No (N)'	System	02 Oct 2020 00:54:34

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3f4a1e8b-6595-4ff5-ad95-6557de26a179'	System	02 Oct 2020 00:54:34
User entered 'None (1)'	System	02 Oct 2020 00:54:34

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:30', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3f4a1e8b-6595-4ff5-ad95-6557de26a179'	System	02 Oct 2020 00:54:34
User entered '01 Oct 2020 19:54'	System	02 Oct 2020 00:54:34

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 14:02'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 2'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:22', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:25', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered 'No (N)'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:12:28', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered 'Yes (Y)'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:28', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered '50'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:33', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered 'None (1)'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:37', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '522fd6b4-1d24-423f-866c-0dd5458d814d'	System	03 Oct 2020 01:13:40
User entered '02 Oct 2020 20:13'	System	03 Oct 2020 01:13:40

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 3'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:10', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered 'None (1)'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:13', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered 'No (N)'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:16', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered 'Yes (Y)'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:21', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered '30'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:24', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered 'None (1)'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ec58c4ec-aa63-4905-b0c7-5211f9d89b14'	System	04 Oct 2020 01:17:29
User entered '03 Oct 2020 20:17'	System	04 Oct 2020 01:17:29

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 4'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '336f7f58-30da-4b88-b4d4-4ab5ad0fb346'	System	05 Oct 2020 01:04:37
User entered 'None (1)'	System	05 Oct 2020 01:04:37

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '336f7f58-30da-4b88-b4d4-4ab5ad0fb346'	System	05 Oct 2020 01:04:37
User entered 'No (N)'	System	05 Oct 2020 01:04:37

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:25', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '336f7f58-30da-4b88-b4d4-4ab5ad0fb346'	System	05 Oct 2020 01:04:37
User entered 'No (N)'	System	05 Oct 2020 01:04:37

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:28', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '336f7f58-30da-4b88-b4d4-4ab5ad0fb346'	System	05 Oct 2020 01:04:37
User entered 'None (1)'	System	05 Oct 2020 01:04:37

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:33', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '336f7f58-30da-4b88-b4d4-4ab5ad0fb346'	System	05 Oct 2020 01:04:37
User entered '04 Oct 2020 20:04'	System	05 Oct 2020 01:04:37

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 5'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:03', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered 'None (1)'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:06', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered 'Yes (Y)'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered '9'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered 'No (N)'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered 'None (1)'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '8a020b9c-60ad-4e24-850b-abc6fb461aa1'	System	06 Oct 2020 14:59:31
User entered '06 Oct 2020 09:59'	System	06 Oct 2020 14:59:31

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 6'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T21:15:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '142d48c3-c6a2-4f9c-8cdc-05353bd60043'	System	07 Oct 2020 02:15:51
User entered 'None (1)'	System	07 Oct 2020 02:15:51

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '142d48c3-c6a2-4f9c-8cdc-05353bd60043'	System	07 Oct 2020 02:15:51
User entered 'No (N)'	System	07 Oct 2020 02:15:51

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '142d48c3-c6a2-4f9c-8cdc-05353bd60043'	System	07 Oct 2020 02:15:51
User entered 'No (N)'	System	07 Oct 2020 02:15:51

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T21:15:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '142d48c3-c6a2-4f9c-8cdc-05353bd60043'	System	07 Oct 2020 02:15:51
User entered 'None (1)'	System	07 Oct 2020 02:15:51

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '142d48c3-c6a2-4f9c-8cdc-05353bd60043'	System	07 Oct 2020 02:15:51
User entered '06 Oct 2020 21:15'	System	07 Oct 2020 02:15:51

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 7'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:39:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9371bbd2-ca7c-40cc-86ad-cee1400aa98d'	System	07 Oct 2020 21:40:14
User entered 'None (1)'	System	07 Oct 2020 21:40:14

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:39:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9371bbd2-ca7c-40cc-86ad-cee1400aa98d'	System	07 Oct 2020 21:40:14
User entered 'No (N)'	System	07 Oct 2020 21:40:14

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:40:01', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9371bbd2-ca7c-40cc-86ad-cee1400aa98d'	System	07 Oct 2020 21:40:14
User entered 'No (N)'	System	07 Oct 2020 21:40:14

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:40:07', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9371bbd2-ca7c-40cc-86ad-cee1400aa98d'	System	07 Oct 2020 21:40:14
User entered 'None (1)'	System	07 Oct 2020 21:40:14

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:10', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9371bbd2-ca7c-40cc-86ad-cee1400aa98d'	System	07 Oct 2020 21:40:14
User entered '07 Oct 2020 16:40'	System	07 Oct 2020 21:40:14

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:14', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:16', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:20', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:22', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:29', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered 'None (0)'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b'	System	01 Oct 2020 15:57:39
User entered 'No (N)'	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T10:57:35', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '66404669-1116-48e8-b68a-7a168109345b' User entered '01 Oct 2020 10:57'	System	01 Oct 2020 15:57:39
	System	01 Oct 2020 15:57:39

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 10:37'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 13:07'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:36', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:40', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'None (0)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered 'No (N)'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-01T19:54:50', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '107d6363-9584-48ab-a748-9aca761f22d3'	System	02 Oct 2020 00:54:57
User entered '01 Oct 2020 19:54'	System	02 Oct 2020 00:54:57

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '01 Oct 2020 14:02'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 2'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:50', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'None (0)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:55', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered 'No (N)'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-02T20:13:58', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '3ab020c3-589a-40f5-a42e-c03878064ea2'	System	03 Oct 2020 01:14:02
User entered '02 Oct 2020 20:13'	System	03 Oct 2020 01:14:02

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 3'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:31', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:33', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:36', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:40', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'None (0)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:45', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered 'No (N)'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-03T20:17:47', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c0321686-e746-4138-aae8-32ee06c4d41c'	System	04 Oct 2020 01:17:50
User entered '03 Oct 2020 20:17'	System	04 Oct 2020 01:17:50

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 4'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:37', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:40', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:45', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:48', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'None (0)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:51', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered 'No (N)'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c345e921b185e504)', Time: '2020-10-04T20:04:53', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '64b34c50-a4fe-46d4-974c-957b6b00df91'	System	05 Oct 2020 01:04:55
User entered '04 Oct 2020 20:04'	System	05 Oct 2020 01:04:55

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 5'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:30', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:32', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T09:59:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:36', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'None (0)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered 'No (N)'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T09:59:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '0fa4092d-d2df-4487-9584-a41d3b8991e0'	System	06 Oct 2020 14:59:47
User entered '06 Oct 2020 09:59'	System	06 Oct 2020 14:59:47

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 6'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:50', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-06T21:15:54', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:15:59', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:16:01', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'None (0)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:16:03', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered 'No (N)'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-06T21:16:07', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'ce83ed2c-bd72-49b3-a7df-6d86f7a76cd6'	System	07 Oct 2020 02:16:11
User entered '06 Oct 2020 21:16'	System	07 Oct 2020 02:16:11

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
Data entry locked.	System	01 Oct 2020 15:25:13
User entered 'Day 7'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:15', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:19', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:27', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:31', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered 'None (0)'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-10-07T16:40:38', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34'	System	07 Oct 2020 21:40:48
User entered 'No (N)'	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fe fd)', Time: '2020-10-07T16:40:41', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '319e4433-c47b-45ef-8388-c11e694b2b34' User entered '07 Oct 2020 16:40'	System	07 Oct 2020 21:40:48
	System	07 Oct 2020 21:40:48

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 15:25:13

US3862119

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:05:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:45:21
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 15:25:13

US3862119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:43

US3862119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '8 Oct 2020'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:43

US3862119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:43

US3862119

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:43
	(b) (4)	

US3862119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:06:47

US3862119

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	08 Oct 2020 22:06:47

US3862119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:19:54

US3862119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:19:54

US3862119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:19:54

US3862119

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:19:54

US3862119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:19:56

US3862119

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	16 Oct 2020 16:19:56

US3862119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 15:18:51

US3862119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '23 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 15:18:51

US3862119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 15:18:51

US3862119

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 15:18:51

US3862119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 15:19:00

US3862119

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	23 Oct 2020 15:19:00

US3862119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:04:54

US3862119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '30 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:04:54

US3862119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:04:54

US3862119

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'VISIT3'	System	30 Oct 2020 18:04:54

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '30 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '08:56'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '30 Oct 2020 08:56'	System	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '97.3' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '84'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'bpm'	System	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '16'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'breaths/min'	System	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '143'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '88'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'mmHg'	System	30 Oct 2020 18:06:13

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39

US3862119

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39

US3862119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:05:03

US3862119

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '30 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:05:03

US3862119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 10:11:22
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'PPD status shipped from site. In Transit.' (Site from DM).	Shetel Anassi (b) (4)	06 Nov 2020 18:45:18
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 30OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:36:19
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	30 Oct 2020 18:05:43

US3862119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '30 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:05:43

US3862119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered '08:46'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:05:43

US3862119

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered '30 Oct 2020 08:46'	System	30 Oct 2020 18:05:43

US3862119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:44:48
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Oct 2020 18:05:12

US3862119

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	30 Oct 2020 18:05:12

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 64'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Have you been exposed to someone with 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 71'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered 'Day 78'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 16:13:50

US3862119

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:11:45
Data entry locked.	System	03 Sep 2020 16:13:50
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 16:13:50

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Headache](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of taste](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of smell](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Sore throat](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Congestion](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Runny nose](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Nausea](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Vomiting](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Diarrhea](#)

Audit	User	Time (GMT)
User entered '0'	Shetel Anassi (b) (4) (b) (4)	09 Dec 2020 16:59:37

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:23', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'Yes (Y)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Have you been exposed to someone with 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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'No (N)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:34', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'Yes (Y)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '0'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '1'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please 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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:49', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:32:59', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'Yes (Y)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Please 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 (bb8b3f009c20fefb)', Time: '2020-12-29T13:33:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2020-12-29T13:33:09', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '88846289-735c-49b7-a56d-9329980bc75c'	System	29 Dec 2020 20:33:21
User entered '29 Dec 2020 13:33:09'	System	29 Dec 2020 20:33:21

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2021-01-05T08:14:22', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eb3e74cf-1339-4a8e-8c5e-541193feabfd'	System	05 Jan 2021 15:14:34
User entered 'No (N)'	System	05 Jan 2021 15:14:34

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Have you been exposed to someone with 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 (bb8b3f009c20fefb)', Time: '2021-01-05T08:14:25', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eb3e74cf-1339-4a8e-8c5e-541193feabfd'	System	05 Jan 2021 15:14:34
User entered 'No (N)'	System	05 Jan 2021 15:14:34

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2021-01-05T08:14:30', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eb3e74cf-1339-4a8e-8c5e-541193feabfd'	System	05 Jan 2021 15:14:34
User entered '05 Jan 2021 08:14:30'	System	05 Jan 2021 15:14:34

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2021-01-13T14:45:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '04d45672-7c11-4d72-ab7c-a54523bd8cc8'	System	13 Jan 2021 20:46:12
User entered 'No (N)'	System	13 Jan 2021 20:46:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Have you been exposed to someone with 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 (bb8b3f009c20fefb)', Time: '2021-01-13T14:45:44', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '04d45672-7c11-4d72-ab7c-a54523bd8cc8'	System	13 Jan 2021 20:46:12
User entered 'No (N)'	System	13 Jan 2021 20:46:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefb)', Time: '2021-01-13T14:45:50', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '04d45672-7c11-4d72-ab7c-a54523bd8cc8'	System	13 Jan 2021 20:46:12
User entered '13 Jan 2021 14:45:50'	System	13 Jan 2021 20:46:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (bb8b3f009c20fefb)', Time: '2021-01-18T05:21:49', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f5b6ddeb-315e-4327-8f38-2f4c15999ca0'	System	18 Jan 2021 11:22:02
User entered 'No (N)'	System	18 Jan 2021 11:22:02

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Have you been exposed to someone with 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 (bb8b3f009c20fefb)', Time: '2021-01-18T05:21:52', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f5b6ddeb-315e-4327-8f38-2f4c15999ca0'	System	18 Jan 2021 11:22:02
User entered 'No (N)'	System	18 Jan 2021 11:22:02

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb8b3f009c20fefdf)', Time: '2021-01-18T05:21:57', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'f5b6ddeb-315e-4327-8f38-2f4c15999ca0'	System	18 Jan 2021 11:22:02
User entered '18 Jan 2021 05:21:57'	System	18 Jan 2021 11:22:02

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-01-25T09:59:39', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eccbce00-bd5c-4b31-95c9-62f6c9e5db10'	System	25 Jan 2021 15:59:51
User entered 'No (N)'	System	25 Jan 2021 15:59:51

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-01-25T09:59:42', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eccbce00-bd5c-4b31-95c9-62f6c9e5db10'	System	25 Jan 2021 15:59:51
User entered 'No (N)'	System	25 Jan 2021 15:59:51

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-01-25T09:59:47', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'eccbce00-bd5c-4b31-95c9-62f6c9e5db10' User entered '25 Jan 2021 09:59:47'	System	25 Jan 2021 15:59:51

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-01T13:16:43', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'b68bebf0-485d-4a55-bfd7-0735121c5ec6' User entered 'No (N)'	System	01 Feb 2021 19:16:53
	System	01 Feb 2021 19:16:53

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-01T13:16:46', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'b68bebf0-485d-4a55-bfd7-0735121c5ec6' User entered 'No (N)'	System	01 Feb 2021 19:16:53
	System	01 Feb 2021 19:16:53

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-01T13:16:49', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'b68bebf0-485d-4a55-bfd7-0735121c5ec6' User entered '01 Feb 2021 13:16:49'	System	01 Feb 2021 19:16:53
	System	01 Feb 2021 19:16:53

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-09T09:17:02', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7dbaa935-5567-447b-b904-44a14cb3d147'	System	09 Feb 2021 15:17:12
User entered 'No (N)'	System	09 Feb 2021 15:17:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-09T09:17:06', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7dbaa935-5567-447b-b904-44a14cb3d147'	System	09 Feb 2021 15:17:12
User entered 'No (N)'	System	09 Feb 2021 15:17:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-09T09:17:09', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7dbaa935-5567-447b-b904-44a14cb3d147'	System	09 Feb 2021 15:17:12
User entered '09 Feb 2021 09:17:09'	System	09 Feb 2021 15:17:12

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-21T15:02:18', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2e497661-544d-44d1-9cdb-2110ab97547b' User entered 'No (N)'	System	21 Feb 2021 21:02:27
	System	21 Feb 2021 21:02:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-21T15:02:21', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2e497661-544d-44d1-9cdb-2110ab97547b' User entered 'No (N)'	System	21 Feb 2021 21:02:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-21T15:02:26', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '2e497661-544d-44d1-9cdb-2110ab97547b' User entered '21 Feb 2021 15:02:26'	System	21 Feb 2021 21:02:27
	System	21 Feb 2021 21:02:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-28T07:58:36-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e693fc40-7f9a-4eff-9590-49b0ad784d21'	System	28 Feb 2021 13:58:48
User entered 'No (N)'	System	28 Feb 2021 13:58:48

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-28T07:58:39-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e693fc40-7f9a-4eff-9590-49b0ad784d21'	System	28 Feb 2021 13:58:48
User entered 'No (N)'	System	28 Feb 2021 13:58:48

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-28T07:58:43-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'e693fc40-7f9a-4eff-9590-49b0ad784d21'	System	28 Feb 2021 13:58:48
User entered '28 Feb 2021 13:58:43'	System	28 Feb 2021 13:58:48

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-09T11:06:32-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '03beb555-8e39-47a6-984d-d5fcd449cf3'	System	09 Mar 2021 17:18:23
User entered 'No (N)'	System	09 Mar 2021 17:18:23

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-09T11:06:35-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '03beb555-8e39-47a6-984d-d5fdb449cf3'	System	09 Mar 2021 17:18:23
User entered 'No (N)'	System	09 Mar 2021 17:18:23

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-09T11:06:39-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '03beb555-8e39-47a6-984d-d5fcd449cf3'	System	09 Mar 2021 17:18:23
User entered '09 Mar 2021 11:06:39'	System	09 Mar 2021 17:18:23

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-28T16:24:16-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9ab5d62c-6ef3-46f5-94ff-ff57193bb88b'	System	28 Mar 2021 22:24:27
User entered 'No (N)'	System	28 Mar 2021 22:24:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-28T16:24:19-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9ab5d62c-6ef3-46f5-94ff-ff57193bb88b'	System	28 Mar 2021 22:24:27
User entered 'No (N)'	System	28 Mar 2021 22:24:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-03-28T16:24:23-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '9ab5d62c-6ef3-46f5-94ff-ff57193bb88b' User entered '28 Mar 2021 16:24:23'	System	28 Mar 2021 22:24:27
	System	28 Mar 2021 22:24:27

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-04T11:14:37-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c8513c2d-6d55-40f9-b999-62fd04a1212b' User entered 'No (N)'	System	04 Apr 2021 16:14:47
	System	04 Apr 2021 16:14:47

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-04T11:14:40-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c8513c2d-6d55-40f9-b999-62fd04a1212b' User entered 'No (N)'	System	04 Apr 2021 16:14:47
	System	04 Apr 2021 16:14:47

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-04T11:14:44-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: 'c8513c2d-6d55-40f9-b999-62fd04a1212b' User entered '04 Apr 2021 11:14:44'	System	04 Apr 2021 16:14:47
	System	04 Apr 2021 16:14:47

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:08-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c' User entered 'Yes (Y)'	System	10 Apr 2021 13:21:46
	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:12-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c' User entered 'No (N)'	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:15-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c' User entered 'No (N)'	System	10 Apr 2021 13:21:46
	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:22-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c'	System	10 Apr 2021 13:21:46
User entered 'Yes (Y)'	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Please 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:32-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c'	System	10 Apr 2021 13:21:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-10T08:21:35-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '346fd3f2-f107-40f4-bf80-a838edbc391c' User entered '10 Apr 2021 08:21:35'	System	10 Apr 2021 13:21:46
	System	10 Apr 2021 13:21:46

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-17T13:21:05-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1e7e00b5-8783-4c61-abcc-9aa6e88e0bc7'	System	17 Apr 2021 18:21:16
User entered 'No (N)'	System	17 Apr 2021 18:21:16

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-17T13:21:08-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1e7e00b5-8783-4c61-abcc-9aa6e88e0bc7'	System	17 Apr 2021 18:21:16
User entered 'No (N)'	System	17 Apr 2021 18:21:16

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-17T13:21:12-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '1e7e00b5-8783-4c61-abcc-9aa6e88e0bc7' User entered '17 Apr 2021 13:21:12'	System	17 Apr 2021 18:21:16
	System	17 Apr 2021 18:21:16

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-24T03:58:53-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7c488f04-4308-4dbe-9ffc-733e67d3a9ae'	System	24 Apr 2021 08:59:04
User entered 'No (N)'	System	24 Apr 2021 08:59:04

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

Have you been exposed to someone with 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 (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-24T03:58:58-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7c488f04-4308-4dbe-9ffc-733e67d3a9ae'	System	24 Apr 2021 08:59:04
User entered 'No (N)'	System	24 Apr 2021 08:59:04

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-04-24T03:59:02-05:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '7c488f04-4308-4dbe-9ffc-733e67d3a9ae' User entered '24 Apr 2021 03:59:02'	System	24 Apr 2021 08:59:04
	System	24 Apr 2021 08:59:04

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:11:45

US3862119

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:05:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:11:45
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:11:45

US3862119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:05:43

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-28T07:58:52-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '5dce8d87-393e-41b0-933e-bae9448950c7'	System	28 Feb 2021 13:59:01
User entered 'No (N)'	System	28 Feb 2021 13:59:01

US3862119

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:05:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (707B66B1-8DCF-4D71-AB58-DDCEC0585D6D)', Time: '2021-02-28T07:58:56-06:00', User OID: 'PatientReportedOutcome (US3862119)', ODM File OID: '5dce8d87-393e-41b0-933e-bae9448950c7'	System	28 Feb 2021 13:59:01
User entered '28 Feb 2021 13:58:56'	System	28 Feb 2021 13:59:01

US3862119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	27 Nov 2020 21:05:38

US3862119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:16
User entered '27 Nov 2020'	(b) (4) Sandra Francisco (b) (4)	27 Nov 2020 21:05:38

US3862119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	27 Nov 2020 21:05:38

US3862119

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:16
User entered empty.	(b) (4) Sandra Francisco (b) (4)	27 Nov 2020 21:05:38

US3862119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:30:16
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	28 Dec 2020 19:24:08

US3862119

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:56:39
User entered 'I'	System	28 Dec 2020 19:24:08

US3862119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	28 Dec 2020 19:24:16

US3862119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '28 Dec 2020'	(b) (4) Sandra Francisco (b) (4)	28 Dec 2020 19:24:16

US3862119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	28 Dec 2020 19:24:16

US3862119

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Sandra Francisco (b) (4)	28 Dec 2020 19:24:16

US3862119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	29 Dec 2020 15:47:16

US3862119

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User entered 'I'	System	29 Dec 2020 15:47:16

US3862119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 19:12:06
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 19:11:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 19:11:58
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 19:11:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Jan 2021 19:11:58
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 15:51:23
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Jan 2021 15:51:23
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	25 Jan 2021 15:51:23
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	25 Jan 2021 15:51:18
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	25 Jan 2021 15:50:39

US3862119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '27 Jan 2021' reason for change: Data Entry Error	Thea Marie Cordero	27 Jan 2021 19:11:58
	(b) (4)	
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	25 Jan 2021 15:51:18
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	25 Jan 2021 15:51:18
User entered empty; reason for change Data Entry Error	Thea Marie Cordero	25 Jan 2021 15:51:18
	(b) (4)	
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	25 Jan 2021 15:50:39
User entered '25 Jan 2021'	Thea Marie Cordero	25 Jan 2021 15:50:39
	(b) (4)	

US3862119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	27 Jan 2021 19:12:06
reason for change: Data Entry Error	Thea Marie Cordero	25 Jan 2021 15:51:18
User entered empty; reason for change Data Entry Error	(b) (4)	25 Jan 2021 15:50:39
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	
	(b) (4)	

US3862119

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Jan 2021 15:50:39
	(b) (4)	

US3862119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:12:12
	(b) (4)	

US3862119

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User entered 'I'	System	27 Jan 2021 19:12:12

US3862119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	25 Feb 2021 15:09:00
	(b) (4)	

US3862119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '25 Feb 2021'	(b) (4) Thea Marie Cordero	25 Feb 2021 15:09:00
	(b) (4)	

US3862119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	25 Feb 2021 15:09:00
	(b) (4)	

US3862119

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Feb 2021 15:09:00
	(b) (4)	

US3862119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	25 Feb 2021 15:09:06
	(b) (4)	

US3862119

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 05:47:31
User entered 'I'	System	25 Feb 2021 15:09:06

US3862119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:11:49
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '31 Mar 2021'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:11:49
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[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 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Clinic (Clinic)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:11:49
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'VISIT4'	System	31 Mar 2021 19:11:49

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '31 Mar 2021'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '09:42'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered '31 Mar 2021 09:42'	System	31 Mar 2021 19:12:55

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '097.7' F	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Other (Other)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'TEMPORAL'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '087'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'bpm'	System	31 Mar 2021 19:12:55

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '014'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'breaths/min'	System	31 Mar 2021 19:12:55

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '124'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'mmHg'	System	31 Mar 2021 19:12:55

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '087'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:12:55
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'mmHg'	System	31 Mar 2021 19:12:55

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10

US3862119

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:05:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10

US3862119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:26
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:05:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '31 Mar 2021'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:26
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:43
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '31 Mar 2021'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:43
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '09:54'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:43
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered '31 Mar 2021 09:54'	System	31 Mar 2021 19:13:43

US3862119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	31 Mar 2021 19:13:49
	(b) (4)	

US3862119

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:10
User entered 'I'	System	31 Mar 2021 19:13:49

US3862119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:12
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	29 Apr 2021 17:02:51
	(b) (4)	

US3862119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:12
	(b) (4)	
User entered '29 Apr 2021'	Carrie Kibler (b) (4)	29 Apr 2021 17:02:51
	(b) (4)	

US3862119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:12
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	29 Apr 2021 17:02:51
	(b) (4)	

US3862119

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:05:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:12
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	29 Apr 2021 17:02:51
	(b) (4)	

US3862119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	30 Apr 2021 16:49:12
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	29 Apr 2021 17:02:54
	(b) (4)	

US3862119

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:05:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 17:02:54

US3862119

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:05:43

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:53:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Apr 2021 04:54:40
Query 'Data is required. Please complete.' answered with 'DATA ENTERED IN ERROR' (Site from System).	Thea Marie Cordero (b) (4)	26 Mar 2021 21:52:46
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 21:52:17
User entered empty; reason for change Data Entry Error	Thea Marie Cordero (b) (4)	26 Mar 2021 21:52:17
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 15:57:17

US3862119

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

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	25 Jan 2021 15:08:43
	(b) (4)	

US3862119

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

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '25 Jan 2021'	Carrie Kibler (b) (4)	25 Jan 2021 15:08:43
	(b) (4)	

US3862119

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

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	25 Jan 2021 15:08:43
	(b) (4)	

US3862119

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

Form: Visit Date

Generated On: 10 Jun 2021 10:05:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 15:08:43

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '25 Jan 2021'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:09:13

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:09:13

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '25 Jan 2021'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	25 Jan 2021 15:49:47
	(b) (4)	

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	25 Jan 2021 15:49:47

US3862119

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

Form: Unblinding

Generated On: 10 Jun 2021 10:05:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered empty.	System	25 Jan 2021 15:49:47

US3862119

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Jan 2021 15:50:18
	(b) (4)	

US3862119

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '25 Jan 2021'	Thea Marie Cordero	25 Jan 2021 15:50:18
	(b) (4)	

US3862119

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '09:27'	Thea Marie Cordero	25 Jan 2021 15:50:18
	(b) (4)	

US3862119

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:05:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '25 Jan 2021 09:27'	System	25 Jan 2021 15:50:18

US3862119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:05:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Jan 2021 15:50:29
	(b) (4)	

US3862119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:05:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '25 Jan 2021'	Thea Marie Cordero	25 Jan 2021 15:50:29
	(b) (4)	

US3862119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:05:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '09:26'	Thea Marie Cordero	25 Jan 2021 15:50:29
	(b) (4)	

US3862119

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:05:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:50:53
User entered '25 Jan 2021 09:26'	System	25 Jan 2021 15:50:29

US3862119

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:05:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User closed query 'Please enter hematuria AE, per source.' (Site from CRA).	(b) (4)	19 Apr 2021 21:40:19
User closed query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:39:49
Query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'SUBJECT HAD 1 DAY EPISODE OF DIARRHEA (AE # 10), ENTERED IN ERROR THAT HE SAW A HEALTH CARE PROVIDER. WAS DOCUMENTED IN SOURCE DOCUMENT' (Site from DM).	Thea Marie Cordero (b) (4)	26 Mar 2021 23:49:45
User opened query 'Per DM CLR: As per Safety Follow-up Diary entry in Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:09:35

US3862119

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:05:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Please enter hematuria AE, per source.'	Thea Marie Cordero	25 Mar 2021 22:32:15
answered with 'WAS ENTERED ON 23 MAR 2021'	(b) (4)	
(Site from CRA).	(b) (4), (b) (6)	
User opened query 'Please enter hematuria AE, per		02 Mar 2021 19:00:09
source.' (Site from CRA).		
DataPoint Verified.		02 Mar 2021 18:44:00
User entered 'Yes (Y)'	Coni Cheesman (b) (4)	14 Sep 2020 21:27:49
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
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)	14 Sep 2020 21:30:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 21:30:50
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 21:30:28
User entered 'Diarrhea'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '3 Sep 2020'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '22:00'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 22:00'	System	14 Sep 2020 21:29:57

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '3 Sep 2020'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
User closed query 'Per CDM: Site response indicates Stop-time is Unknown, however, per page 32 of CCGs, 'if stop time is within 24 hours of dosing time, then the field must be completed. Enter the stop time of the adverse event 24-hour clock format (HH:MM)'. Thank you. Note: If the time is unknown, please try and provide your best estimation to the time. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:29:55
Query 'Per CDM: Site response indicates Stop-time is Unknown, however, per page 32 of CCGs, 'if stop time is within 24 hours of dosing time, then the field must be completed. Enter the stop time of the adverse event 24-hour clock format (HH:MM)'. Thank you. Note: If the time is unknown, please try and provide your best estimation to the time. ' answered with 'Estimated time recorded' (Site from DM).	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:11:09
User entered '23:59' reason for change: Data Entry Error	Chanei Henry (b) (4) (b) (4)	16 Sep 2020 23:10:59
User opened query 'Per CDM: Site response indicates Stop-time is Unknown, however, per page 32 of CCGs, 'if stop time is within 24 hours of dosing time, then the field must be completed. Enter the stop time of the adverse event 24-hour clock format (HH:MM)'. Thank you. Note: If the time is unknown, please try and provide your best estimation to the time. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 09:57:03
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	16 Sep 2020 09:47:44
Query 'Data is required. Please provide.' answered with 'Unknown' (Site from System).	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 23:12:52
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 21:29:57
User entered empty.	Coni Cheesman (b) (4) (b) (4)	14 Sep 2020 21:29:57

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 23:59'	System	16 Sep 2020 23:10:59
User entered empty.	System	14 Sep 2020 21:29:57

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 23:11:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 23:11:53
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	14 Sep 2020 23:11:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:29:57
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 23:11:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 23:11:53
User entered 'None (NONE)' reason for change: Data Entry Error	Coni Cheesman (b) (4)	14 Sep 2020 23:11:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:29:57
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		14 Sep 2020 23:11:53
User entered '0' reason for change: Data Entry Error	Coni Cheesman (b) (4)	14 Sep 2020 23:11:53
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Sep 2020 21:29:57
User entered '1'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '1'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Coni Cheesman (b) (4)	14 Sep 2020 21:29:57
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 21:29:57

US3862119

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 21:29:57

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Gingivitis, LLT: Gum infection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 16:59:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 16:59:57
	(b) (4)	
Data point term sent to Coder	System	30 Oct 2020 16:49:43
User entered 'Gum infection right upper quadrant gum area'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '16 Oct 2020'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 20:12:28
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 'updated' (Site from DM).	Thea Marie Cordero (b) (4)	27 Jan 2021 19:15:04
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Jan 2021 19:14:50
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)	28 Dec 2020 01:53:00
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '15 Jan 2021' reason for change: New Information	Thea Marie Cordero	27 Jan 2021 19:14:50
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '1'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Thea Marie Cordero	27 Jan 2021 19:14:50
New Information	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:49:42
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 16:49:42

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 11:10:18
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Jan 2021 11:10:18
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 19:21:37
Coding entries removed.	Thea Marie Cordero	27 Jan 2021 19:21:35
	(b) (4)	
User entered 'BENIGN INTERNAL HEMORRHOIDS' reason for change: New Information	Thea Marie Cordero	27 Jan 2021 19:21:35
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\23.0.	Coder Import (b) (4)	27 Nov 2020 22:25:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Nov 2020 22:25:20
	(b) (4)	
Data point term sent to Coder	System	27 Nov 2020 21:27:58
User entered 'benign internal hemorrhoids (new diagnosis)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '01 Nov 2020'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Nov 2020 21:27:35

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Nov 2020 21:27:35

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '1'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:27:35
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Nov 2020 21:27:35

US3862119

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Nov 2020 21:27:35

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 21:00:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Jan 2021 21:00:07
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 20:59:37
User entered 'LIGHTHEADEDNESS'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jan 2021 21:03:07
User entered '16 Nov 2020' reason for change: Data Entry Error	Thea Marie Cordero	27 Jan 2021 21:03:07
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jan 2021 20:59:33
User entered 'UN Nov 2020' (non-conformant).	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 21:03:14
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	27 Jan 2021 21:03:14
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	27 Jan 2021 20:59:33
User entered '0'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Jan 2021 20:59:33
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Jan 2021 20:59:33

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4)	02 Mar 2021 18:51:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:07:18
User entered	System	26 Feb 2021 20:06:25
'USA-US121-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	26 Feb 2021 20:06:25

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:25:25
User closed query 'IQVIA Medical query: The narrative case summary in the source document notes hospitalization and ICD placement for ventricular arrhythmia during the same time frame as the SAE for worsening atrial fibrillation. Please consider whether ventricular arrhythmia should be the updated event term or added as a second SAE..' (Site from Safety).		14 Apr 2021 16:50:31
Query 'IQVIA Medical query: The narrative case summary in the source document notes hospitalization and ICD placement for ventricular arrhythmia during the same time frame as the SAE for worsening atrial fibrillation. Please consider whether ventricular arrhythmia should be the updated event term or added as a second SAE..' answered with 'IN NARRATIVE NOTE: HOSPITALIZATION AND ICD PLACEMENT FOR VENTRICULAR ARRHYTHMIA WAS SUBJECT'S REPORT. 25 MAR 2021: MEDICAL RECORDS REVIEWED: SUBJECT WITH HISTORY OF PAROXYSMAL ATRIAL FIBRILLATION (ALREADY UPDATED IN MEDICAL HISTORY). CARDIOLOGISTS NOTES INDICATED SUBJECT HAVING ATRIAL FIBRILLATION EPISODES 4-5 TIMES PER WEEK. AE WAS UPDATED AS WORSENING OF PAROXYSMAL ATRIAL FIBRILLATION. ' (Site from Safety).	Thea Marie Cordero (b) (4)	13 Apr 2021 21:53:15
User opened query 'IQVIA Medical query: The narrative case summary in the source document notes hospitalization and ICD placement for ventricular arrhythmia during the same time frame as the SAE for worsening atrial fibrillation. Please consider whether ventricular arrhythmia should be the updated event term or added as a second SAE..' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:57:51
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 10:02:19

PRODUCTION RELEASE (v12.003
EAB) (1725)

1940 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 10:02:19
User closed query 'Per CDM Re-Query: Site response noted; however, please confirm if condition meets AE criteria and clarify if not related to MH as per below CLR query. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	30 Mar 2021 12:40:01
Data point term sent to Coder	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
Query 'Per CDM Re-Query: Site response noted; however, please confirm if condition meets AE criteria and clarify if not related to MH as per below CLR query. Thank you.' answered with 'SAE UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	System	26 Mar 2021 00:13:02
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	26 Mar 2021 00:12:41
Coding entries removed.	Thea Marie Cordero (b) (4)	26 Mar 2021 00:12:22
User entered 'WORSENING OF PAROXYSMAL ATRIAL FIBRILLATION' reason for change: New Information	Thea Marie Cordero (b) (4)	26 Mar 2021 00:12:22
User opened query 'Per CDM Re-Query: Site response noted; however, please confirm if condition meets AE criteria and clarify if not related to MH as per below CLR query. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:16:04
User closed query 'Per DM CLR: Please verify if this event is a worsening or symptom of the MH condition of ATRIAL FIBRILLATION. If yes, update the AE term to reflect this is worsening and verify Grade to ensure it is greater than the MH condition. Otherwise, confirm if condition meets AE criteria; or clarify if not related to MH.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:16:04
Query 'Per DM CLR: Please verify if this event is a worsening or symptom of the MH condition of ATRIAL FIBRILLATION. If yes, update the AE term to reflect this is worsening and verify Grade to ensure it is greater than the MH condition. Otherwise, confirm if condition meets AE criteria; or clarify if not related to MH.' answered with 'NO' (Site from DM).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:28:29

PRODUCTION RELEASE (v12.003
EAB) (1725)

1941 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please verify if this event is a worsening or symptom of the MH condition of ATRIAL FIBRILLATION. If yes, update the AE term to reflect this is worsening and verify Grade to ensure it is greater than the MH condition. Otherwise, confirm if condition meets AE criteria; or clarify if not related to MH. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:10:10
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular arrhythmia, LLT: Ventricular arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 12:58:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 12:58:49
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:51:57
Data point term sent to Coder	System	25 Feb 2021 15:12:05
User entered 'VENTRICULAR ARRYTHMIA'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:51:58
User entered 'Yes (Y)'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:00
User entered 'No (N)'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:01
User entered 'No (N)'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Most recent follow provided a revised event onset date of 01 Dec 2020. Was this the date when the subject became symptomatic? Please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:03:40
User closed query 'Per medical records, it appears subject began experiencing symptoms (worsening A. fib) at office visit on 18Jan21. Please review and consider updating start date to match onset of symptoms.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 14:42:15
User closed query 'Adverse Event Start Date is before System treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).		20 Apr 2021 21:24:30
User closed query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		20 Apr 2021 21:24:30
User entered '01 Dec 2020' reason for change: New Information	Thea Marie Cordero (b) (4)	20 Apr 2021 21:24:30
Query 'Per medical records, it appears subject began experiencing symptoms (worsening A. fib) at office visit on 18Jan21. Please review and consider updating start date to match onset of symptoms.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from CRA).	Thea Marie Cordero (b) (4)	20 Apr 2021 21:24:07
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	20 Apr 2021 21:24:00
User opened query 'The Start Date for Adverse Event System is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).		20 Apr 2021 21:24:00
Signature has been broken.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:24:00

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Dec 2002' reason for change: New Information	Thea Marie Cordero	20 Apr 2021 21:24:00
User opened query 'Per medical records, it appears subject began experiencing symptoms (worsening A. fib) at office visit on 18Jan21. Please review and consider updating start date to match onset of symptoms.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:53:27
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 16:41:49
DataPoint Un-verified.	Sandra Francisco (b) (4)	12 Mar 2021 17:14:28
User entered '08 Feb 2021' reason for change: Data Entry Error	Sandra Francisco (b) (4)	12 Mar 2021 17:14:28
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:05
User entered '8 Feb 2021'	Thea Marie Cordero	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:38
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4)	02 Mar 2021 18:52:09
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 18:52:09
	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:11
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	25 Feb 2021 15:22:53
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:13
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 15:22:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	25 Feb 2021 15:22:53
User entered '24 Feb 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	25 Feb 2021 15:22:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	25 Feb 2021 15:22:12
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:14
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4)	02 Mar 2021 18:52:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	02 Mar 2021 18:52:19
	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:21
User entered 'Yes (Y)' reason for change: New Information	Thea Marie Cordero	25 Feb 2021 15:22:12
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:23
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:25
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4)	02 Mar 2021 18:52:26
User closed query 'Requires inpatient or prolongation System 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)	26 Feb 2021 14:52:54
Query 'Requires inpatient or prolongation of existing System 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).		26 Feb 2021 14:52:54
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	25 Feb 2021 15:22:12
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	25 Feb 2021 15:22:12
User entered '0'	(b) (4)	25 Feb 2021 15:12:03
	Thea Marie Cordero	
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:28
User entered '23 Feb 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	25 Feb 2021 15:22:12
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:26:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'WILL BE DONE ONCE MEDICAL RECORDS ARE AVAILABLE' (Site from Safety).	Thea Marie Cordero (b) (4)	24 Mar 2021 01:01:39
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:31:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:29
User entered '24 Feb 2021' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	25 Feb 2021 15:22:12
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:30
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	26 Feb 2021 14:52:54
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:32
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:33
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:35
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:36
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:39
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:41
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4)	02 Mar 2021 18:52:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Mar 2021 18:52:44
	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:48
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Sotalol indication was reported as both paroxysmal atrial fibrillation and worsening of paroxysmal atrial fibrillation started on 01Dec2020 and in 2015 with an end date of 04Feb2021. Please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:02:58
User closed query 'Per source, no medications were given for this AE. Please update.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:54:14
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
User closed query 'PV Query: Please confirm if subject received hydrocodone/acetaminophen as it was removed from conmed eCRF but still shows in narrative details. Please reconcile accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:26:18
Query 'PV Query: Please confirm if subject received hydrocodone/acetaminophen as it was removed from conmed eCRF but still shows in narrative details. Please reconcile accordingly.' answered with 'Hydrocodone/acetaminophen was initially ordered by Cardiologist but was changed to Tramadol. Reflected in source document' (Site from Safety).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:58:04
Query 'Per source, no medications were given for this AE. Please update.' answered with 'UPDATED: ERROR ENTRY' (Site from CRA).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:33:30
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	24 Mar 2021 00:32:13
User opened query 'PV Query: Please confirm if subject received hydrocodone/acetaminophen as it was removed from conmed eCRF but still shows in narrative details. Please reconcile accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 17:28:45
User opened query 'Per source, no medications were given for this AE. Please update.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 19:06:16
User entered '1' reason for change: New Information	Thea Marie Cordero (b) (4)	25 Feb 2021 15:22:12
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:50
User entered 'I'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:52:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Thea Marie Cordero	25 Feb 2021 15:22:12
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	25 Feb 2021 15:12:03
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:52:57
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	27 Apr 2021 05:28:46
(Site from DM).		
User closed query 'Please update narrative to note that cardiomyopathy was later determined to not be an AE but medical history. Please also note that hydrocodone/acetaminophen was never filled and taken by subject. Please also include medication changes for A. fib (d/c of sotalol, start/stop carvedilol) done during the course of SAE.'	(b) (4), (b) (6)	23 Apr 2021 14:42:38
(Site from CRA).		
Query 'Please update narrative to note that cardiomyopathy was later determined to not be an AE but medical history. Please also note that hydrocodone/acetaminophen was never filled and taken by subject. Please also include medication changes for A. fib (d/c of sotalol, start/stop carvedilol) done during the course of SAE.'	Thea Marie Cordero	20 Apr 2021 21:34:10
answered with 'ISCHEMIC CARDIOMYOPATHY (PREVIOUSLY REPORTED AS AN ADVERSE EVENT) WAS REMOVED AS AN AE. REPORTED AS PART OF MEDICAL HISTORY (FROM REVIEWED MEDICAL RECORDS). DOCUMENTED IN SOURCE DOCUMENT. HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED WAS INITIALLY DOCUMENTED IN SOURCE DOCUMENT(25 FEB 2021). HOWEVER SUBJECT DID NOT TAKE IT SINCE IT WAS CHANGED TO TRAMADOL BY HIS CARDIOLOGIST ON 26 FEB 2021. HYDROCODONE/ACETAMINOPHEN 5MG/325MG ENTRY WAS INACTIVATED. DOCUMENTED IN SOURCE DOCUMENT. NEW ENTRY FOR SOTALOL DOCUMENTED IN SOURCE DOCUMENT AND EDC'	(b) (4)	
(Site from CRA).		

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please update narrative to note that cardiomyopathy was later determined to not be an AE but medical history. Please also note that hydrocodone/acetaminophen was never filled and taken by subject. Please also include medication changes for A. fib (d/c of sotalol, start/stop carvedilol) done during the course of SAE.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:22:25
User closed query 'Please remove physician names from entry into EDC comments.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:54:56
User opened query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021. Please leave query opened until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:53:25
Query 'Per DM CLR: Narrative = HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED WAS INITIALLY DOCUMENTED IN SOURCE DOCUMENT(25 FEB 2021). HOWEVER SUBJECT DID NOT TAKE IT SINCE IT WAS CHANGED TO TRAMADOL BY HIS CARDIOLOGIST ON 26 FEB 2021. HYDROCODONE/ACETAMINOPHEN 5MG/325MG ENTRY WAS INACTIVATED' (Site from DM).	Thea Marie Cordero (b) (4)	12 Apr 2021 21:31:18
User closed query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021. Please leave query opened until information is received. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:00:18
User opened query 'Per DM CLR: Narrative = HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 23:12:53

PRODUCTION RELEASE (v12.003
EAB) (1725)

1975 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021. Please leave query opened until information is received. ' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	06 Apr 2021 22:31:37
User closed query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 14:33:37
Query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 22:37:52
User opened query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:21:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:20:49
User opened query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021. Please leave query opened until information is received. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 15:20:27
User closed query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:12:54

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:12:51
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:12:48
Query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021.' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:30:42
Query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:30:34
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 13:30:25
User opened query 'PV Query: Please provide the results of the holter monitoring performed on 18 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:01:49
User opened query 'PV Query: Thank you for confirming use of hydrocodone/acetaminophen in eCRF and in response to query. In the narrative, is reported to still have used hydrocodone/acetaminophen as treatment. Please reconcile narrative accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 01:01:18

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED] Thea Marie Cordero (b) (4)	02 Apr 2021 01:00:59 29 Mar 2021 14:22:46

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273-P301 SUBJECT: US3862119 25 FEB 2021 8:30 69 YEARS OLD CAUCASIAN MALE MEDICAL HISTORY: CAD, S/P CABG, ATRIAL FIBRILLATION, HYPERTENSION, HYPERCHOLESTEROLEMIA, SEASONAL ALLERGIES MEDICATION: ATORVASTATIN, LOSARTAN, XARELTO, CETIRIZINE AMENDMENT 6 PROTOCOL UNBLINDED: 25 JAN 2021 RANDOMIZED MRNA 1273 FIRST DOSE: 03 SEP 2020 SECOND DOSE: 01 OCT 2020 1.EVALUATED BY ELECTROPHYSIOLOGIST CARDIOLOGIST ON 08 FEB 2021 FOR EXISTING MILD INTERMITTENT LIGHTHEADEDNESS (PREVIOUSLY REPORTED AS AN ADVERSE EVENT. INITIALLY EVALUATED BY CURRENT CARDIOLOGIST FOR SAME SYMPTOM ON 18 JAN 20021. HAD HOLTER MONITORING ON THE SAME DAY. HAD ECHOCARDIOGRAM AND CARDIAC MRI ON 20 JAN 2021 WHICH SHOWED ISCHEMIC CARDIOMYOPATHY (PREVIOUSLY REPORTED AS AN ADVERSE EVENT). ELECTROPHYSIOLOGIST CARDIOLOGIST RECOMMENDED IMPLANTATION OF DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) FOR VENTRICULAR ARRYTHMIA. 2. ADMITTED IN METHODIST HOSPITAL ON 23 FEB 2021 FOR ICD IMPLANTATION PROCEDURE, DISCHARGED HOME IN STABLE CONDITION ON 24 FEB 2021. 3.DISCHARGE MEDICATIONS: MINOCYCLINE 100 MG 1 CAPSULE PO BID X 5 DAYS (PROPHYLAXIS FOR ICD IMPLANTATION SITE INFECTION) AND HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED FOR PAIN ON IMPLANTATION SITE. 4.25 FEB 2021:DENIED ANY CHEST	Thea Marie Cordero (b) (4)	25 Mar 2021 23:20:42

PRODUCTION RELEASE (v12.003
EAB) (1725)

1979 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
<p>PAIN, PALPITATION AND SHORTNESS OF BREATH, FEVER AND CHILLS. HAD ONE EPISODE OF MILD LIGHTHEADEDNESS YESTERDAY EVENING WHICH RESOLVED SPONTANEOUSLY. CURRENTLY, HAVING INTERMITTENT MODERATE PAIN IN LEFT UPPER ANTERIOR CHEST AREA (IMPLANTATION SITE), AWAITING HYDROCODONE/ACETAMINOPHEN FROM PHARMACY.
5.FOLLOW-UP APPOINTMENT WITH ELECTROPHYSIOLOGIST CARDIOLOGIST WILL BE ON 04 MARCH 2021.
ABOVE INFORMATION DISCUSSED WITH PRINCIPAL INVESTIGATOR. VENTRICULAR ARRHYTHMIA REPORTED AS A SERIOUS ADVERSE EVENT. SUBJECT WILL BE CLOSELY MONITORED. MEDICAL RECORDS WILL BE REQUESTED.
ADDENDUM: 19 FEB 2021 COVID 19 QUALITATIVE PCR TEST- NOT DETECTED'</p>		
reason for change: New Information User closed query 'Per DM CLR: HYPERLIPIDEMIA is noted in the SAE Narrative. However, there is no such condition recorded in the MH eCRF. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:16:42
User closed query 'PV Query: Please confirm if CAGB and hyperlipidemia are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If either are a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:26:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 18:26:26

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'PENDING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	24 Mar 2021 01:02:18
Query 'PV Query: Please confirm if CAGB and hyperlipidemia are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If either are a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'CABG AND HYPERCHOLESTEROLEMIA ARE PART OF MEDICAL HISTORY' (Site from Safety).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:43:05
User entered 'MRNA-1273-P301 SUBJECT	Thea Marie Cordero (b) (4)	24 Mar 2021 00:42:54

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
<p>: US3862119
 25 FEB 2021 8:30
 69 YEARS OLD CAUCASIAN MALE

 />MEDICAL HISTORY: CAD, S/P CABG, ATRIAL FIBRILLATION, HYPERTENSION, HYPERCHOLESTEROLEMIA, SEASONAL ALLERGIES
MEDICATION: ATORVASTATIN, LOSARTAN, XARELTO, CETIRIZINE

AMENDMENT 6 PROTOCOL UNBLINDED: 25 JAN 2021
 />RANDOMIZED MRNA 1273
FIRST DOSE: 03 SEP 2020
SECOND DOSE: 01 OCT 2020
1. HE WAS EVALUATED BY ELECTROPHYSIOLOGIST CARDIOLOGIST ON 08 FEB 2021 FOR EXISTING MILD INTERMITTENT LIGHTHEADEDNESS (PREVIOUSLY REPORTED AS AN ADVERSE EVENT). HE WAS INITIALLY EVALUATED BY (b) (6) (CURRENT CARDIOLOGIST) FOR SAME SYMPTOM ON 18 JAN 20021. HAD HOLTER MONITORING ON THE SAME DAY. HAD ECHOCARDIOGRAM AND CARDIAC MRI ON 20 JAN 2021 WHICH SHOWED ISCHEMIC CARDIOMYOPATHY (PREVIOUSLY REPORTED AS AN ADVERSE EVENT). ELECTROPHYSIOLOGIST CARDIOLOGIST RECOMMENDED IMPLANTATION OF DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) FOR VENTRICULAR ARRYTHMIA.
2. HE WAS ADMITTED IN METHODIST HOSPITAL ON 23 FEB 2021 FOR ICD IMPLANTATION PROCEDURE AND WAS DISCHARGED HOME IN STABLE CONDITION ON 24 FEB 2021.
3. DISCHARGE MEDICATIONS: MINOCYCLINE 100 MG 1 CAPSULE PO BID X 5 DAYS (PROPHYLAXIS FOR ICD IMPLANTATION SITE INFECTION) AND HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED FOR PAIN ON IMPLANTATION SITE.
4. TODAY 25 FEB 2021, SUBJECT DENIED ANY CHEST PAIN, PALPITATION AND</p>		

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
SHORTNESS OF BREATH, FEVER AND CHILLS. HAD ONE EPISODE OF MILD LIGHTHEADEDNESS YESTERDAY EVENING WHICH RESOLVED SPONTANEOUSLY. CURRENTLY, HE IS HAVING INTERMITTENT MODERATE PAIN IN HIS LEFT UPPER ANTERIOR CHEST AREA (IMPLANTATION SITE), AWAITING HYDROCODONE/ACETAMINOPHEN FROM HIS PHARMACY. 5. FOLLOW-UP APPOINTMENT WITH ELECTROPHYSIOLOGIST CARDIOLOGIST WILL BE ON 04 MARCH 2021. ABOVE INFORMATION DISCUSSED WITH MD EL SAHLY (PRINCIPAL INVESTIGATOR). VENTRICULAR ARRYTHMIA REPORTED AS A SERIOUS ADVERSE EVENT. SUBJECT WILL BE CLOSELY MONITORED. MEDICAL RECORDS WILL BE REQUESTED.' reason for change: New Information		
Query 'Per DM CLR: HYPERLIPIDEMIA is noted in the SAE Narrative. However, there is no such condition recorded in the MH eCRF. Please review and update as appropriate. Otherwise, provide clarification.' answered with 'CLARIFICATION: HYPERLIPIDEMIA WAS CHANGED TO HYPERCHOLESTEROLEMIA TO REFLECT SUBJECT'S MEDICAL HISTORY' (Site from DM).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:39:28
Query 'Please remove physician names from entry into EDC comments.' answered with 'DONE' (Site from CRA).	Thea Marie Cordero (b) (4)	24 Mar 2021 00:33:39
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	24 Mar 2021 00:29:53
User entered 'MRNA-1273-P301 SUBJECT	Thea Marie Cordero (b) (4)	24 Mar 2021 00:29:53

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
<p>: US3862119
 25 FEB 2021 8:30
 69 YEARS OLD CAUCASIAN MALE

 >MEDICAL HISTORY: CAD, S/P CABG, ATRIAL FIBRILLATION, HYPERTENSION, HYPERLIPIDEMIA, SEASONAL ALLERGIES
 >MEDICATION: ATORVASTATIN, LOSARTAN, XARELTO, CETIRIZINE

 >AMENDMENT 6 PROTOCOL UNBLINDED: 25 JAN 2021
RANDOMIZED MRNA 1273
 >FIRST DOSE: 03 SEP 2020
SECOND DOSE: 01 OCT 2020
1. HE WAS EVALUATED BY ELECTROPHYSIOLOGIST CARDIOLOGIST ON 08 FEB 2021 FOR EXISTING MILD INTERMITTENT LIGHTHEADEDNESS (PREVIOUSLY REPORTED AS AN ADVERSE EVENT). HE WAS INITIALLY EVALUATED BY (b) (6) (CURRENT CARDIOLOGIST) FOR SAME SYMPTOM ON 18 JAN 2021. HAD HOLTER MONITORING ON THE SAME DAY. HAD ECHOCARDIOGRAM AND CARDIAC MRI ON 20 JAN 2021 WHICH SHOWED ISCHEMIC CARDIOMYOPATHY (PREVIOUSLY REPORTED AS AN ADVERSE EVENT). ELECTROPHYSIOLOGIST CARDIOLOGIST RECOMMENDED IMPLANTATION OF DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) FOR VENTRICULAR ARRHYTHMIA.
2. HE WAS ADMITTED IN METHODIST HOSPITAL ON 23 FEB 2021 FOR ICD IMPLANTATION PROCEDURE AND WAS DISCHARGED HOME IN STABLE CONDITION ON 24 FEB 2021.
3. DISCHARGE MEDICATIONS: MINOCYCLINE 100 MG 1 CAPSULE PO BID X 5 DAYS (PROPHYLAXIS FOR ICD IMPLANTATION SITE INFECTION) AND HYDROCODONE/ACETAMINOPHEN 5MG/325MG 1 TABLET PO EVERY 6 HOURS AS NEEDED FOR PAIN ON IMPLANTATION SITE.
4. TODAY 25 FEB 2021, SUBJECT DENIED ANY CHEST PAIN, PALPITATION AND</p>		

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
SHORTNESS OF BREATH, FEVER AND CHILLS. HAD ONE EPISODE OF MILD LIGHTHEADEDNESS YESTERDAY EVENING WHICH RESOLVED SPONTANEOUSLY. CURRENTLY, HE IS HAVING INTERMITTENT MODERATE PAIN IN HIS LEFT UPPER ANTERIOR CHEST AREA (IMPLANTATION SITE), AWAITING HYDROCODONE/ACETAMINOPHEN FROM HIS PHARMACY. 5. FOLLOW-UP APPOINTMENT WITH ELECTROPHYSIOLOGIST CARDIOLOGIST WILL BE ON 04 MARCH 2021. ABOVE INFORMATION DISCUSSED WITH MD EL SAHLY (PRINCIPAL INVESTIGATOR). VENTRICULAR ARRYTHMIA REPORTED AS A SERIOUS ADVERSE EVENT. SUBJECT WILL BE CLOSELY MONITORED. MEDICAL RECORDS WILL BE REQUESTED.' reason for change: New Information		
User opened query 'Per DM CLR: HYPERLIPIDEMIA is noted in the SAE Narrative. However, there is no such condition recorded in the MH eCRF. Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:10:28
User opened query 'PV Query: Please confirm if CAGB and hyperlipidemia are considered medical history (prior to start of study). If considered MH, please add to MH eCRF. If either are a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:32:28
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:32:16
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:55:05
User opened query 'Please remove physician names from entry into EDC comments.' (Site from CRA).		02 Mar 2021 18:53:47

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Feb 2021 14:51:31
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Feb 2021 14:51:31

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273-P301 Subject: US3862119 25 Feb 2021 8:30 69 years old Caucasian male Medical History: CAD, s/p CABG, Atrial Fibrillation, Hypertension, Hyperlipidemia, Seasonal Allergies Medication: Atorvastatin, Losartan, Xarelto, Cetirizine Amendment 6 Protocol Unblinded: 25 Jan 2021 Randomized mRNA 1273 First dose: 03 Sep 2020 Second dose: 01 Oct 2020 1. He was evaluated by (b) (6) (Electrophysiologist Cardiologist) on 08 Feb 2021 for existing mild intermittent lightheadedness (previously reported as an Adverse Event). He was initially evaluated by (b) (6) (Current Cardiologist) for same symptom on 18 Jan 20021. Had Holter monitoring on the same day. Had Echocardiogram and Cardiac MRI on 20 Jan 2021 which showed Ischemic Cardiomyopathy (previously reported as an Adverse Event). Electrophysiologist Cardiologist recommended implantation of dual chamber implantable cardioverter defibrillator (ICD) for Ventricular Arrhythmia. 2. He was admitted in Methodist Hospital on 23 Feb 2021 for ICD implantation procedure and was discharged home in stable condition on 24 Feb 2021. 3. Discharge medications: Minocycline 100 mg 1 capsule po BID x 5 days (Prophylaxis for ICD implantation site infection) and Hydrocodone/Acetaminophen 5mg/325mg 1 tablet po every 6 hours as needed for pain on implantation site. 4. Today 25 Feb 2021, subject denied any chest pain, palpitation and shortness of breath, fever and chills. Had one episode of mild lightheadedness yesterday evening which resolved spontaneously. Currently, he is having intermittent moderate pain in his left upper anterior chest area (implantation site), awaiting Hydrocodone/Acetaminophen from his pharmacy. 5. Follow-up appointment with Electrophysiologist Cardiologist will be on 04 March 2021. Above information discussed with MD El Sahly (Principal Investigator). Ventricular Arrhythmia	Thea Marie Cordero (b) (4)	26 Feb 2021 14:51:31

PRODUCTION RELEASE (v12.003
EAB) (1725)

1987 of 2968

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
reported as a Serious Adverse Event. Subject will be closely monitored. Medical Records will be requested.' reason for change: New Information User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Feb 2021 15:22:12
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 15:22:12
User entered '0'	System	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 15:12:03

US3862119

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 14:52:54

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: Complications associated with device, HLT: Complications associated with device NEC, PT: Medical device site pain, LLT: Medical device site pain - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:28:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:28:29
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 14:15:23
User entered 'PAIN ON LEFT UPPER ANTERIOR CHEST AREA (ICD IMPLANTATION SITE)'	Thea Marie Cordero	26 Feb 2021 14:14:29
reason for change: New Information	(b) (4)	
Data point term sent to Coder	System	25 Feb 2021 15:16:10
User entered 'PAIN ON LEFT UPPER ANTERIOR CHEST AREA'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '24 Feb 2021'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '1'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	25 Feb 2021 15:15:30
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Feb 2021 15:15:30

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:26:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 00:26:47
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 00:25:43
User entered 'HEMATURIA'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '06 Feb 2021'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '07 Feb 2021'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 00:26:48
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	24 Mar 2021 00:26:48
	(b) (4)	
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Mar 2021 00:25:29
User entered 'Yes (Y)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '1'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Mar 2021 00:26:48
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Mar 2021 00:26:48
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Mar 2021 00:25:29
User entered empty.	Thea Marie Cordero	24 Mar 2021 00:25:29
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 00:26:48
User entered '1'	System	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 00:25:29

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
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)	24 Mar 2021 01:06:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 01:06:50
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 01:06:16
User entered 'DIARRHEA'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '24 Dec 2020'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '24 Dec 2020'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered empty.	Thea Marie Cordero (b) (4)	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Related (RELATED)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

None

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 01:06:28
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Mar 2021 01:06:09
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	24 Mar 2021 01:06:28
	(b) (4)	
User entered '0'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	24 Mar 2021 01:06:09
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 01:06:09

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 16:43:27
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Mar 2021 16:43:27
	(b) (4)	
Data point term sent to Coder	System	26 Mar 2021 16:42:57
User entered 'PREMATURE VENTRICULAR CONTRACTION'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '18 Jan 2021'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty; reason for change Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered '24 Feb 2021'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	Thea Marie Cordero	26 Mar 2021 16:51:49
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
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	26 Mar 2021 16:47:17
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
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	26 Mar 2021 16:42:05
User entered 'Yes (Y)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
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).		26 Mar 2021 16:47:17
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).		26 Mar 2021 16:47:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	26 Mar 2021 16:42:05
User entered '0'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty; reason for change Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered '23 Feb 2021'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty; reason for change Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered '24 Feb 2021'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty; reason for change Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:46
User entered '0'	Thea Marie Cordero (b) (4)	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'I'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Thea Marie Cordero	26 Mar 2021 16:47:17
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:46
	(b) (4)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Mar 2021 16:47:17
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	26 Mar 2021 16:47:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	26 Mar 2021 16:42:05
User entered empty.	Thea Marie Cordero	26 Mar 2021 16:42:05
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 16:47:17
User entered '1'	System	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 16:42:05

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 19:37:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 19:37:47
	(b) (4)	
Data point term sent to Coder	System	31 Mar 2021 19:35:52
User entered 'HEMATURIA'	(b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '1'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 19:35:50

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Dysuria, LLT: Dysuria - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 19:38:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 19:38:35
	(b) (4)	
Data point term sent to Coder	System	31 Mar 2021 19:36:53
User entered 'DYSURIA'	(b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 19:36:34

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Urinary tract lithiasis (excl renal), PT: Calculus urethral, LLT: Urethral calculus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:57:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:57:36
Data point term sent to Coder	System	08 Apr 2021 20:26:39
User entered 'URETHRAL STONE'	(b) (4), (b) (6) (b) (4)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User entered '08 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 20:29:34
User entered '23 Mar 2021'		08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 20:26:14

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Genitourinary tract disorders NEC, HLT: Genital and urinary tract disorders NEC, PT: Urogenital disorder, LLT: Urogenital disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:03:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:03:35
Data point term sent to Coder	System	12 Apr 2021 21:16:56
User entered 'UNDETERMINED UROTHELIAL FINDINGS'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User entered '01 Apr 2021'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 21:21:26
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	12 Apr 2021 21:21:26
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Apr 2021 21:17:22
User entered '0'	Thea Marie Cordero	12 Apr 2021 21:16:19
	(b) (4)	

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	12 Apr 2021 21:17:22
User entered '1'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 21:16:19

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Low grade fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:47:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:47:45
Data point term sent to Coder	System	20 Apr 2021 21:46:48
User entered 'LOW GRADE FEVER'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User entered '28 Feb 2021'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Feb 2021'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[None](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Thea Marie Cordero (b) (4)	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 21:46:45

US3862119

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 10 Jun 2021 10:05:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:46:45

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:05:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	03 Sep 2020 18:14:18

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:43:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:43:26
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Apr 2021 19:42:16 15 Apr 2021 19:41:22
DataPoint Verified.	(b) (4)	15 Apr 2021 15:58:55
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:10:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 21:10:45
Data point term sent to Coder User entered 'Sotalol'	System Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:09:34 03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		19 Apr 2021 21:41:53
User closed query 'Please update to match medical history term per source as paroxysmal atrial fibrillation.' (Site from CRA).		19 Apr 2021 21:41:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:49
Query 'Please update to match medical history term per source as paroxysmal atrial fibrillation.' answered with 'data updated in edc and source doc' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:41:55
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 19:41:22
User entered 'paroxysmal ATRIAL FIBRILLATION' reason for change: Data Entry Error		15 Apr 2021 19:41:22
User opened query 'Please update to match medical history term per source as paroxysmal atrial fibrillation.' (Site from CRA).		15 Apr 2021 15:59:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Atrial Fibrillation'	Trent Davis (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:12:37
Signature has been broken.	Thea Marie Cordero	12 Apr 2021 21:23:22
User signature succeeded.	(b) (4) Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '40'	(b) (4) Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'twice daily (BID)'	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'un UNK 2015'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	09 Feb 2021 20:39:14
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '04 Feb 2021' reason for change: New Information	Carrie Kibler (b) (4)	09 Feb 2021 20:39:14
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:08:47
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
DataPoint Verified.		15 Apr 2021 15:59:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
User entered '2'	System	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
User entered '1'	System	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:10
User entered '804 (804)'	System	03 Sep 2020 21:08:47

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 21:11:55
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	03 Sep 2020 21:11:55
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	03 Sep 2020 21:10:38
User entered 'Atorvastatin'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Coronary Artery Disease'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '80'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un UNK 2015'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:09:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:09:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:09:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 21:09:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 21:16:49
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 Sep 2020 21:16:49
Data point term sent to Coder User entered 'Losartan'	System Trent Davis (b) (4) (b) (4)	03 Sep 2020 21:15:53 03 Sep 2020 21:14:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Hypertension'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '50'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un UNK 2015'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:14:54
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:14:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:14:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 21:14:54

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 21:17:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 21:17:42
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 21:16:55
User entered 'Xarelto'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Atrial fibrillation'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '20'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mg (mg)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un UNK 2015'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:16:08
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:16:08

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:16:08

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 21:16:08

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 07:46:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 07:46:34
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 21:17:57
User entered 'Multi Vitamin'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Prophylaxis for General Health'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'tablet (TABLET)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un UNK 2010'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:17:04
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:17:04

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:17:04

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 21:17:04

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 08:45:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 08:45:31
	(b) (4)	
Data point term sent to Coder	System	03 Sep 2020 21:19:00
User entered 'Vitamin B12'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Prophylaxis for General Health'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '1'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'tablet (TABLET)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un UNK 2015'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Trent Davis (b) (4)	03 Sep 2020 21:18:16
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:18:16

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 21:18:16

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 21:18:16

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 21:27:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	14 Sep 2020 21:27:48
Data point term sent to Coder	System	14 Sep 2020 21:26:15
User entered 'Imodium'	Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Diarrhea'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Per DM CLR: Please update the dose field to reflect the numerical value (e.g. 1) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:31:34
Query 'Per DM CLR: Please update the dose field to reflect the numerical value (e.g. 1) as appropriate. ' answered with 'updated' (Site from DM).	Shetel Anassi (b) (4)	10 Nov 2020 19:40:17
User entered '1' reason for change: Data Entry Error	Shetel Anassi (b) (4)	10 Nov 2020 19:40:09
User opened query 'Per DM CLR: Please update the dose field to reflect the numerical value (e.g. 1) as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 08:02:17
User entered 'one'	Coni Cheesman (b) (4)	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'tablet (TABLET)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'as needed (PRN)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '3 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '3 Sep 2020'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Coni Cheesman (b) (4)	14 Sep 2020 21:25:22
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User entered empty.	System	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User entered empty.	System	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:13
User entered empty.	System	14 Sep 2020 21:25:22

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
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)	27 Jan 2021 19:34:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 19:34:05
Data point term sent to Coder	System	27 Jan 2021 19:32:54
Coding entries removed.	Thea Marie Cordero	27 Jan 2021 19:32:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:22
Data point term sent to Coder	System	08 Oct 2020 22:16:14
User entered 'Acetaminophen'	Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN ON INJECTION SITE POST VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE POST VACCINATION did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 02:29:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN ON INJECTION SITE POST VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE POST VACCINATION did not meet the AE reporting criteria. ' answered with 'THIS SYMPTOM IS PART OF THE EXPECTED LOCAL REACTONEGICITY SYMPTOM AFTER VACCINATION. THIS IS NOT CONSIDERED AN AE' (Site from DM).	Thea Marie Cordero (b) (4)	26 Feb 2021 16:49:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[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 timeframe. If the PAIN ON INJECTION SITE POST VACCINATION is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE POST VACCINATION did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:31:23
User closed query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 08:59:12
Query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' answered with 'UPDATED' (Site from DM).	Thea Marie Cordero (b) (4)	27 Jan 2021 19:33:06
User entered 'PAIN ON INJECTION SITE POST VACCINATION' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Jan 2021 19:32:53
User opened query 'Per DM CLR: Please specify the actual symptoms recorded in the diary (e.g. INJECTION SITE PAIN, HEADACHE etc.). Update and reconcile with AE eCRF if it fits the protocol specified criteria for AE reporting. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:46:49
User entered 'Solicited symptoms'	Chanei Henry (b) (4) (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '500'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once daily (QD)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '1 Oct 2020'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	08 Oct 2020 22:18:26
User entered '3 Oct 2020' reason for change: Data Entry Error	Chanei Henry (b) (4)	08 Oct 2020 22:18:26
	(b) (4)	
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	08 Oct 2020 22:16:09
User entered empty.	Chanei Henry (b) (4)	08 Oct 2020 22:16:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User entered '1'	System	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User entered '1'	System	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:17
User entered '804 (804)'	System	08 Oct 2020 22:16:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 19:51:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 19:51:08
	(b) (4)	
Data point term sent to Coder	System	27 Jan 2021 19:50:23
Coding entries removed.	Thea Marie Cordero	27 Jan 2021 19:49:30
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:26
	(b) (4)	
Data point term sent to Coder	System	08 Oct 2020 22:20:18
User entered 'Acetaminophen'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Per CDM: Prophylaxis=No; however, indication is recorded as health promotion measure (Prophylaxys for Toothache). Please clarify if this was given as a prophylactic or preventative measure. If used for prophylaxis, please update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:52:08
Query 'Per CDM: Prophylaxis=No; however, indication is recorded as health promotion measure (Prophylaxys for Toothache). Please clarify if this was given as a prophylactic or preventative measure. If used for prophylaxis, please update accordingly. Thank you. ' answered with 'updated' (Site from DM).	Carrie Kibler (b) (4)	09 Feb 2021 20:43:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 20:43:15
User opened query 'Per CDM: Prophylaxis=No; however, indication is recorded as health promotion measure (Prophylaxys for Toothache). Please clarify if this was given as a prophylactic or preventative measure. If used for prophylaxis, please update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:00:29
User entered 'No (N)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
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). Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:00:30
User entered 'PROPHYLAXIS FOR TOOTHACHE' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Jan 2021 19:49:36
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:47:05
User entered 'toothache'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '500'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mg (mg)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'other (OTHER)' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Jan 2021 19:49:30
User entered 'as needed (PRN)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'EVERY 4 HOURS AS NEEDED'	Thea Marie Cordero	27 Jan 2021 19:49:30
reason for change: New Information	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un Sep 2020'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Chanei Henry (b) (4)	08 Oct 2020 22:19:21
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 22:19:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 22:19:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 22:19:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:29:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:29:50
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 16:23:29
User entered 'CETRIZINE HYDROCHLORIDE'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'SEASONAL ALLERGIES'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Carrie Kibler (b) (4)	16 Oct 2020 16:23:56
	(b) (4)	
User entered '0.5'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	16 Oct 2020 16:23:56
	(b) (4)	
User entered 'mL (mL)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'as needed (PRN)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'UN UNK 2010'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:01
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:23:01

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:23:01

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 16:23:01

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:31:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Oct 2020 16:31:33
Data point term sent to Coder	System	16 Oct 2020 16:24:32
User entered 'FLU SHOT'	Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'INFLUENZA'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0.5'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '16 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User entered empty.	System	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User entered empty.	System	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:26
User entered empty.	System	16 Oct 2020 16:23:46

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 10:58:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 10:58:14
Data point term sent to Coder	System	30 Oct 2020 16:52:45
User entered 'Levofloxacin'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Gum infection right upper quadrant gum area'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '500'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24 Oct 2020'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)' reason for change: New Information	(b) (4) Sandra Francisco (b) (4)	27 Nov 2020 21:12:36
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '31 Oct 2020' reason for change: New Information	Sandra Francisco (b) (4)	27 Nov 2020 21:12:36
	(b) (4)	
User entered empty.	Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	30 Oct 2020 16:52:14
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User entered '1'	System	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User entered '1'	System	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:30
User entered '804 (804)'	System	30 Oct 2020 16:52:14

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: STOMATOLOGICAL PREPARATIONS, ATC: STOMATOLOGICAL PREPARATIONS, ATC: OTHER AGENTS FOR LOCAL ORAL TREATMENT, PRODUCT: BENZOCAINE, PRODUCTSYNONYM: ORA-JEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Nov 2020 22:38:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Nov 2020 22:38:20
	(b) (4)	
Data point term sent to Coder	System	27 Nov 2020 21:13:53
User entered 'ora-gel'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'GUM INFECTION RIGHT UPPER QUADRANT GUM AREA'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '1'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Other (OTHER)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'application'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'once daily (QD)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Topical (TOPICAL)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'un Nov 2020'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)'	Sandra Francisco (b) (4)	27 Nov 2020 21:13:10
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Nov 2020 21:13:10

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Nov 2020 21:13:10

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Nov 2020 21:13:10

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
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)	28 Jan 2021 00:35:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 00:35:18
Data point term sent to Coder	System	27 Jan 2021 19:27:50
User entered 'ASPIRIN'	Thea Marie Cordero (b) (4)	27 Jan 2021 19:27:25

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'PROPHYLAXIS FOR THROMBOEMBOLIC EVENT' reason for change:	(b) (4)	27 Jan 2021 19:27:45
Data Entry Error	Thea Marie Cordero	27 Jan 2021 19:27:25
User entered 'PROPHYLXIS FOR THROMBOEMBOLIC EVENT'	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '81'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '18 Jan 2021'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:00:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Jan 2021 19:27:25
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 19:27:25

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 19:27:25

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 19:27:25

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:42:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Feb 2021 20:42:39
Data point term sent to Coder	System	09 Feb 2021 20:41:15
User entered 'imodium'	Carrie Kibler (b) (4)	09 Feb 2021 20:40:53
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
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).		15 Apr 2021 14:42:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
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 'AE # 10 WAS ENTERED ON 23 MAR 2021' (Site from DM).	Thea Marie Cordero (b) (4)	25 Mar 2021 22:30:41
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 15:32:06
User entered 'diarrhea'	Carrie Kibler (b) (4)	09 Feb 2021 20:40:53
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '2'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'as needed (PRN)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User entered empty.	System	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User entered empty.	System	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:49
User entered empty.	System	09 Feb 2021 20:40:53

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ADSORBENTS, ATC: BISMUTH PREPARATIONS, PRODUCT: BISMUTH SUBSALICYLATE, PRODUCTSYNONYM: PEPTOBISMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:43:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 20:43:37
Data point term sent to Coder	System	09 Feb 2021 20:42:16
User entered 'peptobismol'	Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'diarrhea'	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '30'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'as needed (PRN)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24 Dec 2020'	(b) (4) Carrie Kibler (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24 Dec 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User entered empty.	System	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User entered empty.	System	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:54
User entered empty.	System	09 Feb 2021 20:41:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:44:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:44:00
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Apr 2021 19:43:17 15 Apr 2021 19:42:26
DataPoint Verified.		15 Apr 2021 16:01:42
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 20:46:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 20:46:37
Data point term sent to Coder	System	09 Feb 2021 20:45:20
Data point term sent to Coder	System	09 Feb 2021 20:43:17
User entered 'carvedilol'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:01:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
User closed query 'Please update to match SAE term of worsening of paroxysmal atrial fibrillation since this was given/adjusted in the course of treatment for the SAE.' (Site from CRA).		19 Apr 2021 21:42:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:49
Query 'Please update to match SAE term of worsening of paroxysmal atrial fibrillation since this was given/adjusted in the course of treatment for the SAE.' answered with 'data updated in edc and source doc ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:43:07
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 19:42:26
User entered 'paroxysmal ATRIAL FIBRILLATION' reason for change: Data Entry Error		15 Apr 2021 19:42:26
User opened query 'Please update to match SAE term of worsening of paroxysmal atrial fibrillation since this was given/adjusted in the course of treatment for the SAE.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 16:01:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'atrial fibrillation' reason for change: Data Entry Error	Carrie Kibler (b) (4)	09 Feb 2021 20:45:08
User entered 'atrial fibrillation'	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:04:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '6.25'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:04:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:04:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:04:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'twice daily (BID)'	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:05:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:05:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:05:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		19 Apr 2021 21:43:10
User closed query 'Per source, start date was 04Feb21. Please update.' (Site from CRA).		19 Apr 2021 21:42:53
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:49
Query 'Per source, start date was 04Feb21. Please update.' answered with 'date correction done to reflect source ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:44:03
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 19:43:27
User entered '04 Feb 2021' reason for change: Data Entry Error		15 Apr 2021 19:43:27
User opened query 'Per source, start date was 04Feb21. Please update.' (Site from CRA).		15 Apr 2021 16:06:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '06 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:06:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:06:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:06:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '07 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:29:33
User entered '06 Feb 2021' reason for change: Data Entry Error		31 Mar 2021 19:28:39
User entered '07 Feb 2021'	Carrie Kibler (b) (4) (b) (4)	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
DataPoint Verified.		15 Apr 2021 16:06:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	09 Feb 2021 20:42:37
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
User entered '2'	System	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
User entered '1'	System	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:38:57
User entered '804 (804)'	System	09 Feb 2021 20:42:37

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: MINOCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:40:10
Data point term sent to Coder	(b) (4)	
User entered 'MINOCYCLINE'	System	26 Feb 2021 16:52:14
	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero (b) (4)	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'PROPHYLAXIS FOR ICD IMPLANTATION SITE INFECTION'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '100'	(b) (4) Thea Marie Cordero (b) (4)	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero (b) (4)	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	26 Feb 2021 16:51:48
	Thea Marie Cordero	
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'twice daily (BID)'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:07:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '24 Feb 2021'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '0'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	17 Mar 2021 17:32:24
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered '28 Feb 2021' reason for change: New Information	Thea Marie Cordero	17 Mar 2021 17:32:24
	(b) (4)	
User entered empty.	Thea Marie Cordero	26 Feb 2021 16:51:48
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
DataPoint Verified.		15 Apr 2021 16:08:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero (b) (4)	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
User entered '2'	System	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
User entered '1'	System	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:17
User entered '804 (804)'	System	26 Feb 2021 16:51:48

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: TRAMADOL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 22:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 22:33:42
Data point term sent to Coder	System	05 Apr 2021 22:32:57
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 22:32:54
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: TRAMADOL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:01:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:01:57
Data point term sent to Coder	System	27 Feb 2021 00:00:31
User entered 'TRAMADOL HCL'	Thea Marie Cordero (b) (4)	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 8). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		15 Apr 2021 14:43:40
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update to Yes as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 14:43:34
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 8). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 22:33:47
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 22:32:54
User entered 'No (N)' reason for change: New Information		05 Apr 2021 22:32:54
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF (AE# 8). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).		02 Apr 2021 19:52:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update to Yes as appropriate. Else, clarify. ' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from DM).	Thea Marie Cordero (b) (4)	17 Mar 2021 17:34:18

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Thea Marie Cordero (b) (4)	17 Mar 2021 17:34:04
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update to Yes as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:42:44
User entered 'No (N)'	Thea Marie Cordero (b) (4)	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 22:32:54
User entered 'PAIN ON LEFT UPPER ANTERIOR CHEST AREA (ICD IMPLANTATION SITE)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 22:32:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'PROPHYLAXIS FOR PAIN ON LEFT UPPER ANTERIOR CHEST AREA (ICD IMPLANTATION SITE)'	(b) (4) Thea Marie Cordero (b) (4)	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '50'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'EVERY 6 HRS AS NEEDED'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '26 Feb 2021'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)' reason for change: New Information	(b) (4) Thea Marie Cordero	17 Mar 2021 17:34:04
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '07 Mar 2021' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 17:34:04
User entered empty.	Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Feb 2021 00:00:23
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User entered empty.	System	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User entered empty.	System	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:21
User entered empty.	System	27 Feb 2021 00:00:23

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
DataPoint Un-verified.		15 Apr 2021 16:09:42
DataPoint Verified.		15 Apr 2021 16:09:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:20
Data point term sent to Coder	System	25 Mar 2021 23:58:22
Data point term sent to Coder	System	25 Mar 2021 23:56:20
User entered 'FENTANYL'	Thea Marie Cordero (b) (4)	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'IMPLANTATION OF DUAL CHAMBER ICD' reason for change: Data Entry Error	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:30
User entered 'IMPLANTATION OF DUAL ICD'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '50'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'ug (ug)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Feb 2021'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Feb 2021'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:56:07
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User entered empty.	System	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User entered empty.	System	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:24
User entered empty.	System	25 Mar 2021 23:56:07

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 09:07:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 09:07:38
Data point term sent to Coder	System	25 Mar 2021 23:57:20
User entered 'VERSED'	Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'IMPLANTATION OF DUAL CHAMBER ICD'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '2'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Thea Marie Cordero (b) (4)	25 Mar 2021 23:57:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Feb 2021'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Feb 2021'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:57:09
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User entered empty.	System	25 Mar 2021 23:57:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User entered empty.	System	25 Mar 2021 23:57:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:28
User entered empty.	System	25 Mar 2021 23:57:09

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ETOMIDATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:10
Data point term sent to Coder	System	25 Mar 2021 23:59:23
User entered 'ETOMIDATE'	Thea Marie Cordero (b) (4)	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'IMPLANTATION OF DUAL CHAMBER ICD'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '6'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	25 Mar 2021 23:58:41
User entered '23 Feb 2021' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	25 Mar 2021 23:58:41
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Mar 2021 23:58:31
User entered empty.	Thea Marie Cordero (b) (4)	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '23 Feb 2021'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) Thea Marie Cordero	25 Mar 2021 23:58:31
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User entered empty.	System	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User entered empty.	System	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:32
User entered empty.	System	25 Mar 2021 23:58:31

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:11:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 14:24:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Apr 2021 14:24:40
Data point term sent to Coder	System	31 Mar 2021 19:31:43
User entered 'METOPROLOL'	(b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:11:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:11:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'PAROXYMAL ATRIAL FIBRILATION'	(b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '12.5'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '08 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 16:12:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 19:30:43

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:11:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 13:11:45
	(b) (4)	
Data point term sent to Coder	System	31 Mar 2021 19:32:44
User entered 'AMOXICILLIN'	(b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'DYSURIA'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '500'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'mg (mg)'	(b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '0'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 19:32:32

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
	(b) (4)	
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)	08 Apr 2021 22:02:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 22:02:57
	(b) (4)	
Data point term sent to Coder	System	08 Apr 2021 20:28:42
User entered 'FLOMAX'	(b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'URETHRAL STONE'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
	(b) (4)	
User entered '0.4'	(b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 20:29:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Apr 2021 20:29:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 20:29:05
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Apr 2021 20:28:21
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 20:28:21

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:25
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 20:53:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 20:53:02
Data point term sent to Coder	System	08 Apr 2021 20:37:03
Data point term sent to Coder	System	08 Apr 2021 20:35:01
User entered 'CEFTRIAXONE'	(b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:26
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:28
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'DUAL CHAMBER DEFRIBILATOR IMPLANTATION' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 20:36:33
User entered 'DUAL CHAMBER DEFRIBILATOR INSERTION'	(b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:29
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '2'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:35
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:37
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:38
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:41
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:43
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:44
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:48
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:49
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		15 Apr 2021 16:13:52
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
DataPoint Verified.		19 Apr 2021 21:44:23
User closed query 'Per source, this is No. Please update.' (Site from CRA).		19 Apr 2021 21:44:02
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:42:49
Query 'Per source, this is No. Please update.' answered with 'data updated to reflect source' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:45:07
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 19:44:36
User entered 'No (N)' reason for change: Data Entry Error		15 Apr 2021 19:44:36
User opened query 'Per source, this is No. Please update.' (Site from CRA).		15 Apr 2021 16:14:12
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
User entered empty.	System	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
User entered empty.	System	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:42
User entered empty.	System	08 Apr 2021 20:34:13

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:56:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:56:00
Data point term sent to Coder	System	20 Apr 2021 21:40:43
User entered 'SOTALOL'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:39:59

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'WORSENING OF PAROXYSMAL ATRIAL FIBRILLATION'	(b) (4) Thea Marie Cordero (b) (4)	20 Apr 2021 21:39:59

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '40'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered empty.	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'ONCE A DAY AS NEEDED'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered empty.	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '01 Dec 2020'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '0'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '04 Feb 2021'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:39:59
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User entered empty.	System	20 Apr 2021 21:39:59

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User entered empty.	System	20 Apr 2021 21:39:59

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:47
User entered empty.	System	20 Apr 2021 21:39:59

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:46:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 21:46:44
Data point term sent to Coder	System	20 Apr 2021 21:45:47
User entered 'TYLENOL'	Thea Marie Cordero (b) (4)	20 Apr 2021 21:45:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'LOW GRADE FEVER'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '500'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered empty.	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'once (ONCE)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered empty.	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered empty.	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '28 Feb 2021'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '0'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered '28 Feb 2021'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'No (N)'	(b) (4) Thea Marie Cordero	20 Apr 2021 21:45:35
	(b) (4)	

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User entered empty.	System	20 Apr 2021 21:45:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User entered empty.	System	20 Apr 2021 21:45:35

US3862119

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 10 Jun 2021 10:05:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:50
User entered empty.	System	20 Apr 2021 21:45:35

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:05:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 19:03:02
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:07:07

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Feb 2021 00:08:02
User entered '16 Nov 2020' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Feb 2021 00:08:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	27 Jan 2021 20:08:49
User entered 'UN Nov 2020' (non-conformant).	Thea Marie Cordero (b) (4)	27 Jan 2021 20:08:49

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:05:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'COLONOSCOPY'	Thea Marie Cordero	27 Jan 2021 20:08:49
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User closed query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.	(b) (4), (b) (6)	02 Mar 2021 03:19:51
' (Site from DM). Query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.	Thea Marie Cordero (b) (4)	26 Feb 2021 16:44:08
' answered with 'SEE UPDATED INDICATION' (Site from DM). User opened query 'Per DM CLR: Indication = OTHER, however, please confirm if the indication could be recorded as one of the available choice (i.e. Diagnostic). Reconcile and update as appropriate, otherwise clarify.	(b) (4), (b) (6)	26 Feb 2021 10:32:57
' (Site from DM). User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	27 Jan 2021 20:10:12
User entered 'Other (OTHER)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Jan 2021 20:10:12
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	27 Jan 2021 20:08:49
User entered 'Medical History (MH)'	Thea Marie Cordero (b) (4)	27 Jan 2021 20:08:49

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:05:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'ROUTINE SCREENING' reason for change: New Information	Thea Marie Cordero	26 Feb 2021 16:43:52
	(b) (4)	
User entered 'GENERAL HEALTH'	Thea Marie Cordero	27 Jan 2021 20:08:49
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:48
DataPoint Verified.		15 Apr 2021 15:58:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '20 Jan 2021'	(b) (4)	
	Thea Marie Cordero	27 Jan 2021 20:09:30
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:05:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:48
DataPoint Verified.		15 Apr 2021 15:58:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'CARDIAC MRI'	(b) (4) Thea Marie Cordero (b) (4)	27 Jan 2021 20:09:30

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:48
DataPoint Verified.		15 Apr 2021 15:58:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'Adverse Event (AE)'	(b) (4) Thea Marie Cordero	27 Jan 2021 20:09:30
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:05:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:48
DataPoint Verified.		15 Apr 2021 15:58:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	27 Jan 2021 20:09:30
	Thea Marie Cordero	
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:59
DataPoint Verified.		15 Apr 2021 15:57:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '18 Jan 2021'	(b) (4)	
	Thea Marie Cordero	27 Jan 2021 20:11:05
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:05:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:59
DataPoint Verified.		15 Apr 2021 15:57:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'HOLTER MONITOR'	(b) (4) Thea Marie Cordero (b) (4)	27 Jan 2021 20:11:05

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:59
DataPoint Verified.		15 Apr 2021 15:57:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
	(b) (4)	
User entered 'Adverse Event (AE)'	Thea Marie Cordero	27 Jan 2021 20:11:05
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:05:43

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:29:59
DataPoint Verified.		15 Apr 2021 15:57:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered empty.	(b) (4)	27 Jan 2021 20:11:05
	Thea Marie Cordero	
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4)	02 Mar 2021 19:04:13
User entered '23 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 19:04:13
	Thea Marie Cordero	26 Feb 2021 16:40:45
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:05:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:04:13
User entered 'IMPLANTATION OF DUAL CHAMBER IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)'	Thea Marie Cordero (b) (4)	26 Feb 2021 16:40:45

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 19:04:13
User entered 'Adverse Event (AE)'	Thea Marie Cordero (b) (4)	26 Feb 2021 16:40:45

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:05:43

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:30:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4)	02 Mar 2021 19:04:13
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:04:13
	Thea Marie Cordero	26 Feb 2021 16:40:45
	(b) (4)	

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:05:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '01 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 20:27:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 20:26:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:22:45

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:05:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'CT OF THE ABDOMEN'	(b) (4), (b) (6)	08 Apr 2021 20:27:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 20:26:31
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	31 Mar 2021 19:22:45

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:05:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:27:04
DataPoint activated with code reason code Data required.		08 Apr 2021 20:26:31
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:22:45

US3862119

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:05:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered empty.	(b) (4)	08 Apr 2021 20:27:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	08 Apr 2021 20:26:31
DataPoint inactivated with code reason code Data not required.		31 Mar 2021 19:22:45

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:43:55
User entered '26/Feb/2021 15:09'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:05:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4)	02 Mar 2021 18:43:55
User entered '26/Feb/2021 15:20'	(b) (4), (b) (6) System	26 Feb 2021 20:20:07

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:05:43

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.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 14:58:15
DataPoint Verified.		02 Mar 2021 18:43:55
User entered '1'		26 Feb 2021 20:20:07

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '15/Mar/2021 10:58'	(b) (4) System	15 Mar 2021 14:58:34

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:05:43

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)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
User entered 'I'		15 Mar 2021 14:58:34

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '24/Mar/2021 18:27'	(b) (4) System	24 Mar 2021 18:27:18

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:05:43

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)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	26 Mar 2021 13:47:24
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 18:27:18

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered '26/Mar/2021 08:47'	(b) (4) System	26 Mar 2021 13:47:40

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:05:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:18:10
DataPoint Verified.		14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:47:40

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered '06/Apr/2021 10:40'	(b) (4) System	06 Apr 2021 14:40:37

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:05:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 16:18:10
DataPoint Verified.		14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:35:24
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 14:40:37

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:29
User entered 'USA-US121-2021-MRNA-1273-P301000002'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Yes (Y)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'No (N)'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Thea Marie'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'Hana'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'Cordero'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'El Sahly'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:38:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
Reviewed for Safety.	(b) (4)	24 Mar 2021 18:27:05
Un-reviewed for Safety.	System	15 Mar 2021 14:58:34
DataPoint Un-verified.	System	15 Mar 2021 14:58:34
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	15 Mar 2021 14:58:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.		26 Feb 2021 20:09:36
User entered 'One Baylor Plaza'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'Houston'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'TX'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered '77030'	System	26 Feb 2021 20:06:25

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:23:55
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:43:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 20:09:36
User entered 'US'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 10:05:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	21 Apr 2021 16:18:21
User entered '6'	System	06 Apr 2021 14:40:37
User entered '5'	System	26 Mar 2021 13:47:40
User entered '4'	System	24 Mar 2021 18:27:18
User entered '3'	System	15 Mar 2021 14:58:34
User entered '2'	System	26 Feb 2021 20:20:07
User entered '1'	System	26 Feb 2021 20:09:15

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:05:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
	(b) (4)	
User entered '21/Apr/2021 12:18'	System	21 Apr 2021 16:18:21

US3862119

Folder: SAE USA-US121-2021-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:05:43

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.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:09
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 16:18:21