

US3352070 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:10:24

All time stamps listed in this document are displayed in GMT

US3352070

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Participant ID

US3352070

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

US3352070

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Date of Informed Consent (<i>dd MMM yyyy</i>)	13 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3352070

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Apr 2021 20:34:05

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Condition	ASTIGMATISM BILATERAL
Start date (dd MMM yyyy)	UN UNK 1969
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1969
Start Year (derived)	1969
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Condition	CURRENT TOBACCO USER
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Condition	MELANOMA OF THE LOWER BACK
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Condition	PURULENT OTORRHEA OF RIGHT EAR
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:15
Height (xxx.x)	180 cm
Weight (xxx.x)	76 kg
BMI (xxx.x)	23.45679 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 20:34:05

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 20:34:05

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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

Visit date (dd MMM yyyy)	13 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 103850

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 20:34:06

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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)	13 AUG 2020
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 11:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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)	13 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 13:16
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 12:46 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 12:46

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 AUG 2020

Collection time (00:00-23:59)

12:17 (24 HR)

Collection date and time (derived)

13 AUG 2020 12:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:55	13 AUG 2020 11:55
Nasopharyngeal Swab 2	No		

US3352070

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

13 AUG 2020 13:25

PC Open Date & Time

13 AUG 2020 13:06

PC Close Date & Time

13 AUG 2020 15:36

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	13 AUG 2020 18:10
PC Open Date & Time	13 AUG 2020 16:31
PC Close Date & Time	14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

15 AUG 2020 06:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

97.8 °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

15 AUG 2020 19:13

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 14:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 16:27

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 15:38

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

13 AUG 2020 13:26

PC Open Date & Time

13 AUG 2020 13:06

PC Close Date & Time

13 AUG 2020 15:36

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

13 AUG 2020 18:11

PC Open Date & Time

13 AUG 2020 16:31

PC Close Date & Time

14 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 06:13

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:13

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

16 AUG 2020 14:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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)**

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

18 AUG 2020 16:28

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

19 AUG 2020 15:38

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 13:26
PC Open Date & Time	13 AUG 2020 13:06
PC Close Date & Time	13 AUG 2020 15:36

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:11
PC Open Date & Time	13 AUG 2020 16:31
PC Close Date & Time	14 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 06:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:14
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 14:31
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

Yes ☐

PC Time stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 16:28
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 15:39
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3352070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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)	8 SEP 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 11:38
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	98 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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)	8 SEP 2020
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 13:11
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	93 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3352070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 12:41 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 12:41

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

US3352070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 SEP 2020
Collection time (00:00-23:59)	12:02 (24 HR)
Collection date and time (derived)	8 SEP 2020 12:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	8 SEP 2020 11:45
Nasopharyngeal Swab 2	No		

US3352070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

08 SEP 2020 13:27

PC Open Date & Time

08 SEP 2020 13:01

PC Close Date & Time

08 SEP 2020 15:31

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	08 SEP 2020 18:01
PC Open Date & Time	08 SEP 2020 16:26
PC Close Date & Time	09 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:20

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:10

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 15:46

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 17:50

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

08 SEP 2020 13:27

PC Open Date & Time

08 SEP 2020 13:01

PC Close Date & Time

08 SEP 2020 15:31

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

08 SEP 2020 18:01

PC Open Date & Time

08 SEP 2020 16:26

PC Close Date & Time

09 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 17:24

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

11 SEP 2020 18:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

12 SEP 2020 15:46

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

13 SEP 2020 19:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

14 SEP 2020 17:50

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 13:28
PC Open Date & Time	08 SEP 2020 13:01
PC Close Date & Time	08 SEP 2020 15:31

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:02
PC Open Date & Time	08 SEP 2020 16:26
PC Close Date & Time	09 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 18:21
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:25
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 15:47
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

102 of 2266

EAB) (1725)

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:25
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

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 ☒

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 17:51
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3352070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	07 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 11:35
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3352070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 OCT 2020
Collection time (00:00-23:59)	11:50 (24 HR)
Collection date and time (derived)	07 OCT 2020 11:50

US3352070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:06

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 OCT 2020 08:59:45
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 11:19:24

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 09:49:21
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 NOV 2020 03:16:21

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 00:02:26
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 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):	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 NOV 2020 10:06:28
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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="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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 11:25:42

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 07:22:12

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

20 DEC 2020 10:03:42

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

29 DEC 2020 16:13:40

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

12 JAN 2021 13:30:22

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

20 JAN 2021 07:37:15

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 10:00:24
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

03 FEB 2021 16:17:21

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

09 FEB 2021 10:54:59

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 187

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 16:27:27

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

09 MAR 2021 16:25:44

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

17 MAR 2021 11:57:39

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 18:02:38

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 <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	31 MAR 2021 02:03:13
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 <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	06 APR 2021 09:25:08
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 11:48:12

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 10:39:43

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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="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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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°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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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12 FEB 2022 00:01

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16 FEB 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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02 MAR 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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16 MAR 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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23 MAR 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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°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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 726

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

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

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

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

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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="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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2022 00:01
Patient Cloud Close Date & Time	12 OCT 2022 23:59

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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"/>

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3352070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:10:24

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		27 FEB 2021 16:27:39

US3352070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:34:05

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments MULTIPLE ATTEMPTS, NO ANSWER

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

UNABLE TO GET IN CONTACT
WITH SUBJECT.

If Contact Not Made, please provide Comments

US3352070

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 20:33:38

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352070

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3352070

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3352070

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3352070

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3352070

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352070

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:10:24

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352070

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

Visit date (dd MMM yyyy)	16 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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US3352070

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Date of updated informed consent (dd MMM yyyy) 16 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) 16 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 _____

US3352070

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

Collection date (dd MMM yyyy)	16 JAN 2021
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Collection time (00:00-23:59)	14:00 (24 HR)
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Collection date and time (derived)	16 JAN 2021 14:00
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US3352070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	13:50
Collection Date and Time (derived)	16 JAN 2021 13:50

US3352070

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID	
Adverse event	LEFT DISTAL TIBIA FRACTURE
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)	25 SEP 2020
Start time (00:00-23:59)	11:00 (24 HR)
AE start date and time (derived)	25 SEP 2020 11:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID USA-US066-2021-MRNA-1273-P30
1000008

Adverse event WORSENING OF LEFT DISTAL
TIBIA FRACTURE

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 10 MAR 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 True

Hospital Admission Date (dd MMM yyyy) 10 MAR 2021

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

SUBJECT REPORTED HAVING
RECONSTRUCTIVE SURGERY
FOR PREVIOUS FRACTURE OF
LEFT DISTAL TIBIA. HE IS
BEING HOSPITALIZED SINCE 13
MARCH 2021. HE REPORTED
THAT HE IS RECEIVING IV
ANTIBIOTICS. HE DOES NOT
KNOW WHEN HE IS GOING TO
BE DISCHARGE. HE DENIES
HAVING COVID 19 SYMPTOMS.
MEDICAL RECORDS WILL BE
REQUESTED TO INCLUDE
DETAILS OF THE EVENT
INCLUDING TREATMENT.

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

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID USA-US066-2021-MRNA-1273-P30
1000008

Adverse event LEFT POPLITEAL DEEP VEIN
THROMBOSIS

Was this a medically-attended AE? Yes ☒
No ☐

Was this a Solicited Adverse Reaction? Yes ☐
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐
No ☒

Start date (dd MMM yyyy) 10 MAR 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 True

Hospital Admission Date (dd MMM yyyy) 10 MAR 2021

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☒
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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	

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

MEDICAL RECORDS OBTAINED
FROM THE HOSPITAL
REVEALED THAT SUBJECT
PRESENTED TO THE
EMERGENCY DEPARTMENT
COMPLAINING OF LEFT LOWER
LEG PAIN, SWELLING, REDNESS
AND DRAINAGE. ALSO
REPORTED SHORTNESS OF
BREATH AND SUBJECTIVE
FEVER. SUBJECT WITH A
HISTORY OF LEFT DISTAL
TIBIA FRACTURE. UPON
FURTHER EVALUATION AND
TESTING HE WAS ADMITTED
TO THE HOSPITAL WITH A LEFT
POPLITEAL DEEP VEIN
THROMBOSIS, SEPSIS AND
CELLULITIS OF HIS RIGHT LEG.
PENDING TO OBTAIN MORE
INFORMATION ABOUT
CURRENT HOSPITALIZATION
STATUS.

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

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID	USA-US066-2021-MRNA-1273-P30 1000008
Adverse event	CELLULITIS OF LEFT LEG
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	5 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 type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

MEDICAL RECORDS OBTAINED
FROM THE HOSPITAL
REVEALED THAT SUBJECT
PRESENTED TO THE
EMERGENCY DEPARTMENT
COMPLAINING OF LEFT LOWER
LEG PAIN, SWELLING, REDNESS
AND DRAINAGE. ALSO
REPORTED SHORTNESS OF
BREATH AND SUBJECTIVE
FEVER. SUBJECT WITH A
HISTORY OF LEFT DISTAL
TIBIA FRACTURE. UPON
FURTHER EVALUATION AND
TESTING HE WAS ADMITTED
TO THE HOSPITAL WITH A LEFT
POPLITEAL DEEP VEIN
THROMBOSIS, SEPSIS AND
CELLULITIS OF HIS RIGHT LEG.
PENDING TO OBTAIN MORE
INFORMATION ABOUT
CURRENT HOSPITALIZATION
STATUS.

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID	USA-US066-2021-MRNA-1273-P30 1000008
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 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 type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 11:04:42

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID	USA-US066-2021-MRNA-1273-P30 1000011
Adverse event	WOUND INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	20 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	
INFORMATION OBTAINED FROM MEDICAL RECORDS. ANTIBIOTICS LISTED BUT NO NAME OF MEDICATIONS ARE PROVIDED.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#) 0

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 11:04:42

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

Yes ☒

No ☐

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT DISTAL TIBIA FRACTURE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication HCL ACETAMINOPHEN
OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication LEFT DISTAL TIBIA FRACTURE

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	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 checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT POPLITEAL DEEP VEIN
THROMBOSIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 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)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication AMBIEN

Prophylaxis Yes ☐
No ☒

Indication SLEEP

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

BEDTIME AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication MAXIPIME SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS OF RIGHT LEG

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication ENOXAPARIN SODIUM

Prophylaxis Yes ☐
No ☒

Indication LEFT POPLITEAL DEEP VEIN
THROMBOSIS

Dose per administration 0.75

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	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)	11 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication LEFT POPLITEAL DEEP VEIN
THROMBOSIS

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	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)	11 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 1250

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 12 HOURS

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	17 MAR 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"/>	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 50

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

If dose unit is Other, specify 600 MG / 50 ML

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 8 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication VALIUM

Prophylaxis Yes ☐
No ☒

Indication LEFT POPLITEAL DEEP VEIN
THROMBOSIS

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication VANCOGIN AND SODIUM
CHLORIDE 0.9 %

Prophylaxis Yes ☐
No ☒

Indication SEPSIS

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 DEC 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"/>

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 MAR 2021	MRI LEFT FOOT WITH AND WITHOUT CONTRAST.	Adverse Event	
13 MAR 2021	MRI ANKLE WITH AND WITHOUT CONTRAST LEFT	Adverse Event	
10 MAR 2021	US DOPPLER LOWER EXTREMITY VENOUS LEFT.	Adverse Event	
10 MAR 2021	RA CHEST 1 VIEW	Diagnostic	
11 MAR 2021	RA ANKLE PORTABLE LEFT	Adverse Event	
13 MAR 2021	IRRIGATION AND DEBRIDEMENT LEFT ANKLE	Adverse Event	
13 MAR 2021	REMOVAL OF HARWARE ANKLE SURGERY	Adverse Event	
10 MAR 2021	CT ANGIOGRAM OF PULMONARY ARTERIES WITH CONTRAST	Adverse Event	
10 MAR 2021	COVID 19 ANTIGEN BD	Diagnostic	
10 MAR 2021	ECG	Diagnostic	

US3352070

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:10:24

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:10:24

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 ☐

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/MAR/2021 13:19
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 08:33
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/APR/2021 06:20
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/APR/2021 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	20/APR/2021 06:24
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 20:33:37

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000008
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/APR/2021 08:58
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 21:23:16

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000011
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 21:23:16

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000011
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 06:22
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

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 21:23:16

Generated On: 09 Jun 2021 17:10:24

SAEID	USA-US066-2021-MRNA-1273-P301000011
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	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	28/APR/2021 06:18
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

US3352070 (Prod: Research Centers of America - ERG)

US3352070

Form: Participant Creation

Generated On: 09 Jun 2021 17:10:24

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'US3352070'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:50:01

US3352070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:10
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:46:20

US3352070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:10
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:50:02

US3352070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:10
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 18:46:20

US3352070

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:10
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'SCRN'	System	13 Aug 2020 18:46:20

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:50:03

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '54'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'YEARS'	System	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '55'	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Male (M)'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:24

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:17
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:46:54

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'Aug 2020'	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '2020'	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Amendment 2 (2)'	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 15:50:02

US3352070

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:24

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:24
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'l'	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:27
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Sara Gomez (b) (4) (b) (4)	13 Aug 2020 17:21:13

US3352070

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:10:24

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:32
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:47:32

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:53:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 18:53:20
Data point term sent to Coder	System	13 Aug 2020 18:52:38
User entered 'ASTIGMATISM BILATERAL'	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'UN UNK 1969'	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'Jan 1969'	System	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '1969'	System	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	13 Aug 2020 18:52:00

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 04:20:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 04:20:15
Data point term sent to Coder	System	13 Aug 2020 18:52:38
User entered 'CURRENT TOBACCO USER'	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'UN UNK 1983'	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'Jan 1983'	System	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '1983'	System	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	13 Aug 2020 18:52:25

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin melanomas (excl ocular), PT: Malignant melanoma, LLT: Melanoma - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:36:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:36:06
Data point term sent to Coder	System	14 Apr 2021 18:31:11
User entered 'Melanoma of the lower back'	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:30:13

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Mastoiditis, LLT: Unspecified mastoiditis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:42:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:42:50
Data point term sent to Coder	System	14 Apr 2021 18:32:13
User entered 'Unspecified mastoiditis bilateral'	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:31:31

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:33:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:33:57
Data point term sent to Coder	System	14 Apr 2021 18:33:14
User entered 'Chronic Cough'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:06

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Aural disorders NEC, HLT: Ear disorders NEC, PT: Otorrhoea, LLT: Otorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:46:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 09:46:42
Data point term sent to Coder	System	14 Apr 2021 18:34:16
User entered 'Purulent Otorrhea of right ear'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:33:45

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcohol abuse, LLT: Alcohol abuse - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:35:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 18:35:52
Data point term sent to Coder	System	14 Apr 2021 18:35:16
User entered 'Alcohol Abuse'	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:36
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	14 Apr 2021 18:34:18

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:15'	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '13 Aug 2020 11:15'	System	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '180' cm	(b) (4), (b) (6)	13 Aug 2020 18:53:36
DataPoint set to visible.	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Weight \(.xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '76' kg	(b) (4), (b) (6)	13 Aug 2020 18:53:36
DataPoint set to visible.	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
Amendment Manager: User entered '23.45679'	System	16 Sep 2020 23:55:22
User entered '23.5'	System	13 Aug 2020 18:53:36
DataPoint set to visible.	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'kg/m2'	System	13 Aug 2020 18:53:36
DataPoint set to visible.	System	13 Aug 2020 17:21:46

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.		27 Apr 2021 15:31:42
Data hard locked.		27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 10:43:55
Query 'Data is required. Please provide.' answered with 'NOT DONE' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:53:43
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 18:53:36
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.		27 Apr 2021 15:31:42
Data hard locked.		27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'bpm'	System	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'breaths/min'	System	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'mmHg'	System	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'mmHg'	System	13 Aug 2020 18:53:36

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:42
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06

US3352070

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.		27 Apr 2021 15:31:42
Data hard locked.		27 Apr 2021 11:29:06

US3352070

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:46
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:54:01

US3352070

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:46
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 12:15:10
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 17:48:42
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:54:01

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User closed query 'Is subject at risk of exposure? What is the subject's risk of exposure?' (Site from CRA).	(b) (4), (b) (6)	08 Sep 2020 19:45:10
Query 'Is subject at risk of exposure? What is the subject's risk of exposure?' answered with 'Subject location put them at risk, subject lives in south Florida. ' (Site from CRA).	Wanda Delgado (b) (4)	31 Aug 2020 19:51:59
User opened query 'Is subject at risk of exposure? What is the subject's risk of exposure?' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 18:37:04
User entered 'I'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:24

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:32
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:51
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
DataPoint Verified.	(b) (4), (b) (6)	08 Sep 2020 19:45:21
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:55:05

US3352070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:55:18

US3352070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:55:18

US3352070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Aug 2020 18:55:18

US3352070

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'VISIT1'	System	13 Aug 2020 18:55:18

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:25:22

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:11:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:11:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 16:25:22
User entered '103850' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:25:22

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 16:25:22

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

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)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:46

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

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)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:46

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:46

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:46

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:55:46

US3352070

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:24

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:33:50
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	03 Nov 2020 20:59:05
User entered 'No (N)'	Matthew Muniz (b) (4)	03 Nov 2020 20:58:57
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:28:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:19:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:01:53

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:15'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered '13 Aug 2020 11:15'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '36.8' C	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '91'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'bpm'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '16'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'breaths/min'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '96'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'mmHg'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '71'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'mmHg'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:24

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered missing code ND - Not Done.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 05:27:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'POST-DOSE VITAL SIGNS WERE COMPLETED 30 MIN AFTER DOSING AS PER PROTOCOL' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 18:59:34
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 18:58:02
User entered '13:16'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered '13 Aug 2020 13:16'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '36.7' C	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '83'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'bpm'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'breaths/min'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '113'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'mmHg'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '72'	(b) (4), (b) (6)	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'mmHg'	System	13 Aug 2020 18:58:02

US3352070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 18:59:50

US3352070

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:59:50

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '12:46'	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered '13 Aug 2020 12:46'	System	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Left Arm (LEFT ARM)'	Sara Gomez (b) (4)	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'ONCE'	System	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 17:22:33

US3352070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 19:00:25

US3352070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 19:00:25

US3352070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '12:17'	(b) (4), (b) (6)	13 Aug 2020 19:00:25

US3352070

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered '13 Aug 2020 12:17'	System	13 Aug 2020 19:00:25

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:55'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered '13 Aug 2020 11:55'	System	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered empty.	System	13 Aug 2020 19:00:43

US3352070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 19:00:52

US3352070

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:36
User entered 'I'	System	13 Aug 2020 19:00:52

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:25:22', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '949fa183-02ac-428b-88db-e06d439ef1c2'	System	13 Aug 2020 17:25:49
User entered 'Yes (Y)'	System	13 Aug 2020 17:25:49

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:25:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '949fa183-02ac-428b-88db-e06d439ef1c2'	System	13 Aug 2020 17:25:49
User entered '97.4'	System	13 Aug 2020 17:25:49

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:25:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '949fa183-02ac-428b-88db-e06d439ef1c2'	System	13 Aug 2020 17:25:49
User entered 'No (N)'	System	13 Aug 2020 17:25:49

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:25:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '949fa183-02ac-428b-88db-e06d439ef1c2'	System	13 Aug 2020 17:25:49
User entered '13 Aug 2020 13:25'	System	13 Aug 2020 17:25:49

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:09:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '5d3426d0-abee-4e40-9854-e7098e7fd261'	System	13 Aug 2020 22:10:10
User entered 'Yes (Y)'	System	13 Aug 2020 22:10:10

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:09:43', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '5d3426d0-abee-4e40-9854-e7098e7fd261'	System	13 Aug 2020 22:10:10
User entered '98.6'	System	13 Aug 2020 22:10:10

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:09:51', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '5d3426d0-abee-4e40-9854-e7098e7fd261'	System	13 Aug 2020 22:10:10
User entered 'No (N)'	System	13 Aug 2020 22:10:10

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:10:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '5d3426d0-abee-4e40-9854-e7098e7fd261'	System	13 Aug 2020 22:10:10
User entered '13 Aug 2020 18:10'	System	13 Aug 2020 22:10:10

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 16:31'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 2'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:11:56', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16ae348b-cd35-43b3-bdc1-7ccf636f0649'	System	15 Aug 2020 10:12:44
User entered 'Yes (Y)'	System	15 Aug 2020 10:12:44

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:12:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16ae348b-cd35-43b3-bdc1-7ccf636f0649'	System	15 Aug 2020 10:12:44
User entered '98.4'	System	15 Aug 2020 10:12:44

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:12:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16ae348b-cd35-43b3-bdc1-7ccf636f0649'	System	15 Aug 2020 10:12:44
User entered 'No (N)'	System	15 Aug 2020 10:12:44

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:12:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16ae348b-cd35-43b3-bdc1-7ccf636f0649'	System	15 Aug 2020 10:12:44
User entered '15 Aug 2020 06:12'	System	15 Aug 2020 10:12:44

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 3'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:12:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbc028fd-966e-41b7-8cdf-6a370cff5c66'	System	15 Aug 2020 23:13:09
User entered 'Yes (Y)'	System	15 Aug 2020 23:13:09

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:12:51', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbc028fd-966e-41b7-8cdf-6a370cff5c66'	System	15 Aug 2020 23:13:09
User entered '97.8'	System	15 Aug 2020 23:13:09

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:12:55', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbc028fd-966e-41b7-8cdf-6a370cff5c66'	System	15 Aug 2020 23:13:09
User entered 'No (N)'	System	15 Aug 2020 23:13:09

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbc028fd-966e-41b7-8cdf-6a370cff5c66'	System	15 Aug 2020 23:13:09
User entered '15 Aug 2020 19:13'	System	15 Aug 2020 23:13:09

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 4'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:29:57', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '64a24654-104c-401f-bb0e-a75032ccd92b'	System	16 Aug 2020 18:30:30
User entered 'Yes (Y)'	System	16 Aug 2020 18:30:30

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:07', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '64a24654-104c-401f-bb0e-a75032ccd92b'	System	16 Aug 2020 18:30:30
User entered '98.4'	System	16 Aug 2020 18:30:30

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:14', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '64a24654-104c-401f-bb0e-a75032ccd92b'	System	16 Aug 2020 18:30:30
User entered 'No (N)'	System	16 Aug 2020 18:30:30

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '64a24654-104c-401f-bb0e-a75032ccd92b'	System	16 Aug 2020 18:30:30
User entered '16 Aug 2020 14:30'	System	16 Aug 2020 18:30:30

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 5'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 6'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:27:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c258cb88-82d2-413f-a6bc-f55b6103c0ab'	System	18 Aug 2020 20:27:54
User entered 'Yes (Y)'	System	18 Aug 2020 20:27:54

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:27:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c258cb88-82d2-413f-a6bc-f55b6103c0ab'	System	18 Aug 2020 20:27:54
User entered '98.5'	System	18 Aug 2020 20:27:54

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:27:42', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c258cb88-82d2-413f-a6bc-f55b6103c0ab'	System	18 Aug 2020 20:27:54
User entered 'No (N)'	System	18 Aug 2020 20:27:54

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:27:50', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c258cb88-82d2-413f-a6bc-f55b6103c0ab'	System	18 Aug 2020 20:27:54
User entered '18 Aug 2020 16:27'	System	18 Aug 2020 20:27:54

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 7'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbca134d-f285-4125-92aa-396cfa647815'	System	19 Aug 2020 19:38:38
User entered 'Yes (Y)'	System	19 Aug 2020 19:38:38

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbca134d-f285-4125-92aa-396cfa647815'	System	19 Aug 2020 19:38:38
User entered '98.5'	System	19 Aug 2020 19:38:38

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:28', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbca134d-f285-4125-92aa-396cfa647815'	System	19 Aug 2020 19:38:38
User entered 'No (N)'	System	19 Aug 2020 19:38:38

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:33', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dbca134d-f285-4125-92aa-396cfa647815'	System	19 Aug 2020 19:38:38
User entered '19 Aug 2020 15:38'	System	19 Aug 2020 19:38:38

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:25:57', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95ffde9b-b838-44f7-9ffc-fad6ca18822d'	System	13 Aug 2020 17:26:25
User entered 'None (1)'	System	13 Aug 2020 17:26:25

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:01', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95ffde9b-b838-44f7-9ffc-fad6ca18822d'	System	13 Aug 2020 17:26:25
User entered 'No (N)'	System	13 Aug 2020 17:26:25

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:04', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95ffde9b-b838-44f7-9ffc-fad6ca18822d'	System	13 Aug 2020 17:26:25
User entered 'No (N)'	System	13 Aug 2020 17:26:25

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:16', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95ffde9b-b838-44f7-9ffc-fad6ca18822d'	System	13 Aug 2020 17:26:25
User entered 'None (1)'	System	13 Aug 2020 17:26:25

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95ffde9b-b838-44f7-9ffc-fad6ca18822d'	System	13 Aug 2020 17:26:25
User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:26:25

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:10:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '14cf49d8-6a2a-461f-b9ea-be8ca96d9236'	System	13 Aug 2020 22:11:10
User entered 'None (1)'	System	13 Aug 2020 22:11:10

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:10:37', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '14cf49d8-6a2a-461f-b9ea-be8ca96d9236'	System	13 Aug 2020 22:11:10
User entered 'No (N)'	System	13 Aug 2020 22:11:10

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:10:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '14cf49d8-6a2a-461f-b9ea-be8ca96d9236'	System	13 Aug 2020 22:11:10
User entered 'No (N)'	System	13 Aug 2020 22:11:10

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:10:55', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '14cf49d8-6a2a-461f-b9ea-be8ca96d9236'	System	13 Aug 2020 22:11:10
User entered 'None (1)'	System	13 Aug 2020 22:11:10

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '14cf49d8-6a2a-461f-b9ea-be8ca96d9236'	System	13 Aug 2020 22:11:10
User entered '13 Aug 2020 18:11'	System	13 Aug 2020 22:11:10

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 16:31'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 2'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:12:48', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7dd0231a-1e7a-4c01-b9a5-218c1c317acf'	System	15 Aug 2020 10:13:26
User entered 'None (1)'	System	15 Aug 2020 10:13:26

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7dd0231a-1e7a-4c01-b9a5-218c1c317acf'	System	15 Aug 2020 10:13:26
User entered 'No (N)'	System	15 Aug 2020 10:13:26

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:12:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7dd0231a-1e7a-4c01-b9a5-218c1c317acf'	System	15 Aug 2020 10:13:26
User entered 'No (N)'	System	15 Aug 2020 10:13:26

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:08', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7dd0231a-1e7a-4c01-b9a5-218c1c317acf'	System	15 Aug 2020 10:13:26
User entered 'None (1)'	System	15 Aug 2020 10:13:26

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7dd0231a-1e7a-4c01-b9a5-218c1c317acf'	System	15 Aug 2020 10:13:26
User entered '15 Aug 2020 06:13'	System	15 Aug 2020 10:13:26

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 3'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:13', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6cc74644-61c5-4bab-9bae-19bfc9e40676'	System	15 Aug 2020 23:13:35
User entered 'None (1)'	System	15 Aug 2020 23:13:35

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:17', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6cc74644-61c5-4bab-9bae-19bfc9e40676'	System	15 Aug 2020 23:13:35
User entered 'No (N)'	System	15 Aug 2020 23:13:35

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6cc74644-61c5-4bab-9bae-19bfc9e40676'	System	15 Aug 2020 23:13:35
User entered 'No (N)'	System	15 Aug 2020 23:13:35

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6cc74644-61c5-4bab-9bae-19bfc9e40676'	System	15 Aug 2020 23:13:35
User entered 'None (1)'	System	15 Aug 2020 23:13:35

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:32', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6cc74644-61c5-4bab-9bae-19bfc9e40676'	System	15 Aug 2020 23:13:35
User entered '15 Aug 2020 19:13'	System	15 Aug 2020 23:13:35

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 4'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c082895b-cfc8-40c6-afae-4c6ebc085426'	System	16 Aug 2020 18:31:04
User entered 'None (1)'	System	16 Aug 2020 18:31:04

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c082895b-cfc8-40c6-afae-4c6ebc085426'	System	16 Aug 2020 18:31:04
User entered 'No (N)'	System	16 Aug 2020 18:31:04

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:45', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c082895b-cfc8-40c6-afae-4c6ebc085426'	System	16 Aug 2020 18:31:04
User entered 'No (N)'	System	16 Aug 2020 18:31:04

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c082895b-cfc8-40c6-afae-4c6ebc085426'	System	16 Aug 2020 18:31:04
User entered 'None (1)'	System	16 Aug 2020 18:31:04

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:30:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c082895b-cfc8-40c6-afae-4c6ebc085426'	System	16 Aug 2020 18:31:04
User entered '16 Aug 2020 14:30'	System	16 Aug 2020 18:31:04

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 5'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 6'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:27:58', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '526090c2-e480-40d5-ab4f-ddf6d8f7358b'	System	18 Aug 2020 20:28:23
User entered 'None (1)'	System	18 Aug 2020 20:28:23

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '526090c2-e480-40d5-ab4f-ddf6d8f7358b'	System	18 Aug 2020 20:28:23
User entered 'No (N)'	System	18 Aug 2020 20:28:23

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '526090c2-e480-40d5-ab4f-ddf6d8f7358b'	System	18 Aug 2020 20:28:23
User entered 'No (N)'	System	18 Aug 2020 20:28:23

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '526090c2-e480-40d5-ab4f-ddf6d8f7358b'	System	18 Aug 2020 20:28:23
User entered 'None (1)'	System	18 Aug 2020 20:28:23

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '526090c2-e480-40d5-ab4f-ddf6d8f7358b'	System	18 Aug 2020 20:28:23
User entered '18 Aug 2020 16:28'	System	18 Aug 2020 20:28:23

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 7'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '78df662f-439c-4fa5-8207-2680ecb8be44'	System	19 Aug 2020 19:38:59
User entered 'None (1)'	System	19 Aug 2020 19:38:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:45', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '78df662f-439c-4fa5-8207-2680ecb8be44'	System	19 Aug 2020 19:38:59
User entered 'No (N)'	System	19 Aug 2020 19:38:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:48', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '78df662f-439c-4fa5-8207-2680ecb8be44'	System	19 Aug 2020 19:38:59
User entered 'No (N)'	System	19 Aug 2020 19:38:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '78df662f-439c-4fa5-8207-2680ecb8be44'	System	19 Aug 2020 19:38:59
User entered 'None (1)'	System	19 Aug 2020 19:38:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:38:56', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '78df662f-439c-4fa5-8207-2680ecb8be44'	System	19 Aug 2020 19:38:59
User entered '19 Aug 2020 15:38'	System	19 Aug 2020 19:38:59

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:43', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:46', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered 'None (0)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:53', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bdfc6'	System	13 Aug 2020 17:27:02
User entered 'No (N)'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T13:26:58', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '11cd6164-3d87-4476-b278-df60e9bfd6c6'	System	13 Aug 2020 17:27:02
User entered '13 Aug 2020 13:26'	System	13 Aug 2020 17:27:02

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 13:06'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 15:36'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:18', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:24', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'None (0)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered 'No (N)'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-13T18:11:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7a67d6f5-1025-486a-b96d-02f7f4d7805a'	System	13 Aug 2020 22:11:44
User entered '13 Aug 2020 18:11'	System	13 Aug 2020 22:11:44

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Aug 2020 16:31'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 2'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:32', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:13:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:14:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'None (0)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:14:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered 'No (N)'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T06:14:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '765b4c80-839c-4113-8a8c-fe5106ab9080'	System	15 Aug 2020 10:14:17
User entered '15 Aug 2020 06:14'	System	15 Aug 2020 10:14:17

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 3'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:37', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:44', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:13:58', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:14:04', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'None (0)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:14:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered 'No (N)'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-15T19:14:25', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '24aaa2ac-81d7-4650-a3ad-c5a23d642385'	System	15 Aug 2020 23:14:31
User entered '15 Aug 2020 19:14'	System	15 Aug 2020 23:14:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 4'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:18', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:22', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:25', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'None (0)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered 'No (N)'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-16T14:31:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'db5d0f45-c12a-4c8a-b028-f0fc74948a29'	System	16 Aug 2020 18:31:40
User entered '16 Aug 2020 14:31'	System	16 Aug 2020 18:31:40

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 5'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 6'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:25', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:43', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:46', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'None (0)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered 'No (N)'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-18T16:28:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '9d81ca64-ec02-44b2-aafe-b771b933fc96'	System	18 Aug 2020 20:29:05
User entered '18 Aug 2020 16:28'	System	18 Aug 2020 20:29:05

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 7'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:01', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:04', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:07', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:14', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'None (0)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered 'No (N)'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-08-19T15:39:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c7311053-8cee-4a9d-97b5-729a36209880'	System	19 Aug 2020 19:39:31
User entered '19 Aug 2020 15:39'	System	19 Aug 2020 19:39:31

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 17:22:33

US3352070

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:33:59

US3352070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 16:33:59

US3352070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Aug 2020 16:33:59

US3352070

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 16:33:59

US3352070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 16:37:14

US3352070

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:01
User entered 'I'	System	20 Aug 2020 16:37:14

US3352070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	28 Aug 2020 14:37:25

US3352070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '28 Aug 2020'	Yulexis Amestoy (b) (4)	28 Aug 2020 14:37:25

US3352070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	28 Aug 2020 14:37:25

US3352070

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered empty.	Yulexis Amestoy (b) (4)	28 Aug 2020 14:37:25

US3352070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	28 Aug 2020 14:37:31

US3352070

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User entered 'I'	System	28 Aug 2020 14:37:31

US3352070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	03 Sep 2020 16:24:56

US3352070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '3 Sep 2020'	Yulexis Amestoy (b) (4)	03 Sep 2020 16:24:56

US3352070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	03 Sep 2020 16:24:56

US3352070

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Yulexis Amestoy (b) (4)	03 Sep 2020 16:24:56

US3352070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	03 Sep 2020 16:25:04

US3352070

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:28
User entered 'I'	System	03 Sep 2020 16:25:04

US3352070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:42

US3352070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:41:54
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Data confirmed, per protocol, there is a -3 day window for visit 2.' (Site from System).	Wanda Delgado (b) (4)	08 Sep 2020 17:48:47
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Sep 2020 17:48:42
User entered '8 Sep 2020'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:42

US3352070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:42

US3352070

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'VISIT2'	System	08 Sep 2020 17:48:42

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User accepted default value 'Pre-Dose (PREDOSE)'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '8 Sep 2020'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:38'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '8 Sep 2020 11:38'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '36.7' C	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:50:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Sep 2020 17:50:14
User entered 'Oral (Oral)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	08 Sep 2020 17:50:14
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Sep 2020 17:50:02
User entered empty.	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '98'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'bpm'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '16'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'breaths/min'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '116'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'mmHg'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '79'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'mmHg'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User accepted default value 'Post-Dose (POSTDOSE)'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '8 Sep 2020'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '13:11'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '8 Sep 2020 13:11'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '36.7' C	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Oral (Oral)'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '93'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'bpm'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '12'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'breaths/min'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '102'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'mmHg'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '72'	Wanda Delgado (b) (4)	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'mmHg'	System	08 Sep 2020 17:50:02

US3352070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Wanda Delgado (b) (4)	08 Sep 2020 17:47:34

US3352070

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Wanda Delgado (b) (4)	08 Sep 2020 17:47:34

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '8 Sep 2020'	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '12:41'	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '8 Sep 2020 12:41'	System	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'ONCE'	System	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:24

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 16:54:44

US3352070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:12

US3352070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '8 Sep 2020'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:12

US3352070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '12:02'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:12

US3352070

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '8 Sep 2020 12:02'	System	08 Sep 2020 17:48:12

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:24

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '8 Sep 2020'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:45'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '8 Sep 2020 11:45'	System	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Wanda Delgado (b) (4)	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered empty.	System	08 Sep 2020 17:48:29

US3352070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	08 Sep 2020 17:47:23

US3352070

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:44
User entered '1'	System	08 Sep 2020 17:47:23

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:26:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dc1cc305-bda0-49ac-92a4-94b6a281a4f4'	System	08 Sep 2020 17:27:12
User entered 'Yes (Y)'	System	08 Sep 2020 17:27:12

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:26:57', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dc1cc305-bda0-49ac-92a4-94b6a281a4f4'	System	08 Sep 2020 17:27:12
User entered '98.3'	System	08 Sep 2020 17:27:12

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dc1cc305-bda0-49ac-92a4-94b6a281a4f4'	System	08 Sep 2020 17:27:12
User entered 'No (N)'	System	08 Sep 2020 17:27:12

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:08', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dc1cc305-bda0-49ac-92a4-94b6a281a4f4'	System	08 Sep 2020 17:27:12
User entered '08 Sep 2020 13:27'	System	08 Sep 2020 17:27:12

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 15:31'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:00:45', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3139a83a-d18d-43db-970f-1d57c03fc199'	System	08 Sep 2020 22:01:25
User entered 'Yes (Y)'	System	08 Sep 2020 22:01:25

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3139a83a-d18d-43db-970f-1d57c03fc199'	System	08 Sep 2020 22:01:25
User entered '98.6'	System	08 Sep 2020 22:01:25

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3139a83a-d18d-43db-970f-1d57c03fc199'	System	08 Sep 2020 22:01:25
User entered 'No (N)'	System	08 Sep 2020 22:01:25

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3139a83a-d18d-43db-970f-1d57c03fc199'	System	08 Sep 2020 22:01:25
User entered '08 Sep 2020 18:01'	System	08 Sep 2020 22:01:25

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 16:26'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 2'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:19:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a09a31e5-81dd-4bed-8bd1-78ad94b7a954'	System	09 Sep 2020 22:20:18
User entered 'Yes (Y)'	System	09 Sep 2020 22:20:18

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a09a31e5-81dd-4bed-8bd1-78ad94b7a954'	System	09 Sep 2020 22:20:18
User entered '98.6'	System	09 Sep 2020 22:20:18

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a09a31e5-81dd-4bed-8bd1-78ad94b7a954'	System	09 Sep 2020 22:20:18
User entered 'No (N)'	System	09 Sep 2020 22:20:18

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:14', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a09a31e5-81dd-4bed-8bd1-78ad94b7a954'	System	09 Sep 2020 22:20:18
User entered '09 Sep 2020 18:20'	System	09 Sep 2020 22:20:18

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 3'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:20:07', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'f8b2e0c5-b878-415a-83cd-00304b76319a'	System	10 Sep 2020 21:20:32
User entered 'Yes (Y)'	System	10 Sep 2020 21:20:32

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:20:16', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'f8b2e0c5-b878-415a-83cd-00304b76319a'	System	10 Sep 2020 21:20:32
User entered '98.6'	System	10 Sep 2020 21:20:32

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:20:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'f8b2e0c5-b878-415a-83cd-00304b76319a'	System	10 Sep 2020 21:20:32
User entered 'No (N)'	System	10 Sep 2020 21:20:32

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:20:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'f8b2e0c5-b878-415a-83cd-00304b76319a'	System	10 Sep 2020 21:20:32
User entered '10 Sep 2020 17:20'	System	10 Sep 2020 21:20:32

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 4'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:10:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '60151d0e-e35e-4231-9736-e47e997b5b3b'	System	11 Sep 2020 22:10:57
User entered 'Yes (Y)'	System	11 Sep 2020 22:10:57

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:10:43', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '60151d0e-e35e-4231-9736-e47e997b5b3b' User entered '98.6'	System	11 Sep 2020 22:10:57
	System	11 Sep 2020 22:10:57

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:10:48', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '60151d0e-e35e-4231-9736-e47e997b5b3b'	System	11 Sep 2020 22:10:57
User entered 'No (N)'	System	11 Sep 2020 22:10:57

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:10:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '60151d0e-e35e-4231-9736-e47e997b5b3b'	System	11 Sep 2020 22:10:57
User entered '11 Sep 2020 18:10'	System	11 Sep 2020 22:10:57

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 5'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:45:46', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '523d378c-8e27-4f58-a3a1-9b3cac73720f'	System	12 Sep 2020 19:46:09
User entered 'Yes (Y)'	System	12 Sep 2020 19:46:09

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:45:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '523d378c-8e27-4f58-a3a1-9b3cac73720f' User entered '98.5'	System	12 Sep 2020 19:46:09
	System	12 Sep 2020 19:46:09

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:45:58', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '523d378c-8e27-4f58-a3a1-9b3cac73720f'	System	12 Sep 2020 19:46:09
User entered 'No (N)'	System	12 Sep 2020 19:46:09

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '523d378c-8e27-4f58-a3a1-9b3cac73720f'	System	12 Sep 2020 19:46:09
User entered '12 Sep 2020 15:46'	System	12 Sep 2020 19:46:09

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 6'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:28', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e1aff49c-a9f7-4719-ada6-dd1532d1614b'	System	13 Sep 2020 23:24:50
User entered 'Yes (Y)'	System	13 Sep 2020 23:24:50

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e1aff49c-a9f7-4719-ada6-dd1532d1614b'	System	13 Sep 2020 23:24:50
User entered '98.6'	System	13 Sep 2020 23:24:50

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e1aff49c-a9f7-4719-ada6-dd1532d1614b'	System	13 Sep 2020 23:24:50
User entered 'No (N)'	System	13 Sep 2020 23:24:50

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e1aff49c-a9f7-4719-ada6-dd1532d1614b'	System	13 Sep 2020 23:24:50
User entered '13 Sep 2020 19:24'	System	13 Sep 2020 23:24:50

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 7'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2359b9d9-0f8b-4f70-8bed-3cc3c449314a'	System	14 Sep 2020 21:50:22
User entered 'Yes (Y)'	System	14 Sep 2020 21:50:22

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:08', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2359b9d9-0f8b-4f70-8bed-3cc3c449314a'	System	14 Sep 2020 21:50:22
User entered '98.6'	System	14 Sep 2020 21:50:22

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2359b9d9-0f8b-4f70-8bed-3cc3c449314a'	System	14 Sep 2020 21:50:22
User entered 'No (N)'	System	14 Sep 2020 21:50:22

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:17', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2359b9d9-0f8b-4f70-8bed-3cc3c449314a'	System	14 Sep 2020 21:50:22
User entered '14 Sep 2020 17:50'	System	14 Sep 2020 21:50:22

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:19', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3174f67-ce3c-4145-8fb9-404727fc3576'	System	08 Sep 2020 17:27:43
User entered 'None (1)'	System	08 Sep 2020 17:27:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:24', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3174f67-ce3c-4145-8fb9-404727fc3576'	System	08 Sep 2020 17:27:43
User entered 'No (N)'	System	08 Sep 2020 17:27:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3174f67-ce3c-4145-8fb9-404727fc3576'	System	08 Sep 2020 17:27:43
User entered 'No (N)'	System	08 Sep 2020 17:27:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3174f67-ce3c-4145-8fb9-404727fc3576'	System	08 Sep 2020 17:27:43
User entered 'None (1)'	System	08 Sep 2020 17:27:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:39', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3174f67-ce3c-4145-8fb9-404727fc3576'	System	08 Sep 2020 17:27:43
User entered '08 Sep 2020 13:27'	System	08 Sep 2020 17:27:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 15:31'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7c9a9541-1f72-4686-a76c-69e93f26f026'	System	08 Sep 2020 22:01:57
User entered 'None (1)'	System	08 Sep 2020 22:01:57

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7c9a9541-1f72-4686-a76c-69e93f26f026'	System	08 Sep 2020 22:01:57
User entered 'No (N)'	System	08 Sep 2020 22:01:57

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7c9a9541-1f72-4686-a76c-69e93f26f026'	System	08 Sep 2020 22:01:57
User entered 'No (N)'	System	08 Sep 2020 22:01:57

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7c9a9541-1f72-4686-a76c-69e93f26f026'	System	08 Sep 2020 22:01:57
User entered 'None (1)'	System	08 Sep 2020 22:01:57

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:01:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7c9a9541-1f72-4686-a76c-69e93f26f026'	System	08 Sep 2020 22:01:57
User entered '08 Sep 2020 18:01'	System	08 Sep 2020 22:01:57

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 16:26'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 2'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '337c34a4-774b-4b63-9e15-025d75dac752'	System	09 Sep 2020 22:20:47
User entered 'None (1)'	System	09 Sep 2020 22:20:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:29', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '337c34a4-774b-4b63-9e15-025d75dac752'	System	09 Sep 2020 22:20:47
User entered 'No (N)'	System	09 Sep 2020 22:20:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:33', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '337c34a4-774b-4b63-9e15-025d75dac752'	System	09 Sep 2020 22:20:47
User entered 'No (N)'	System	09 Sep 2020 22:20:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '337c34a4-774b-4b63-9e15-025d75dac752'	System	09 Sep 2020 22:20:47
User entered 'None (1)'	System	09 Sep 2020 22:20:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:42', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '337c34a4-774b-4b63-9e15-025d75dac752'	System	09 Sep 2020 22:20:47
User entered '09 Sep 2020 18:20'	System	09 Sep 2020 22:20:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 3'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:24:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e01f3802-3c5f-418c-8d5f-f3d8f3cd2a37'	System	10 Sep 2020 21:25:01
User entered 'None (1)'	System	10 Sep 2020 21:25:01

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:24:44', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e01f3802-3c5f-418c-8d5f-f3d8f3cd2a37'	System	10 Sep 2020 21:25:01
User entered 'No (N)'	System	10 Sep 2020 21:25:01

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:24:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e01f3802-3c5f-418c-8d5f-f3d8f3cd2a37'	System	10 Sep 2020 21:25:01
User entered 'No (N)'	System	10 Sep 2020 21:25:01

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:24:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e01f3802-3c5f-418c-8d5f-f3d8f3cd2a37'	System	10 Sep 2020 21:25:01
User entered 'None (1)'	System	10 Sep 2020 21:25:01

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:24:55', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e01f3802-3c5f-418c-8d5f-f3d8f3cd2a37'	System	10 Sep 2020 21:25:01
User entered '10 Sep 2020 17:24'	System	10 Sep 2020 21:25:01

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 4'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '67d67570-8ba0-4e60-9aab-77d1dda63e9f'	System	11 Sep 2020 22:11:47
User entered 'None (1)'	System	11 Sep 2020 22:11:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '67d67570-8ba0-4e60-9aab-77d1dda63e9f'	System	11 Sep 2020 22:11:47
User entered 'No (N)'	System	11 Sep 2020 22:11:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:13', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '67d67570-8ba0-4e60-9aab-77d1dda63e9f'	System	11 Sep 2020 22:11:47
User entered 'No (N)'	System	11 Sep 2020 22:11:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:18', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '67d67570-8ba0-4e60-9aab-77d1dda63e9f'	System	11 Sep 2020 22:11:47
User entered 'None (1)'	System	11 Sep 2020 22:11:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '67d67570-8ba0-4e60-9aab-77d1dda63e9f'	System	11 Sep 2020 22:11:47
User entered '11 Sep 2020 18:11'	System	11 Sep 2020 22:11:47

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 5'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:11', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '51e583ad-2b96-47b1-8082-dc9e85288403'	System	12 Sep 2020 19:46:34
User entered 'None (1)'	System	12 Sep 2020 19:46:34

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '51e583ad-2b96-47b1-8082-dc9e85288403'	System	12 Sep 2020 19:46:34
User entered 'No (N)'	System	12 Sep 2020 19:46:34

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '51e583ad-2b96-47b1-8082-dc9e85288403'	System	12 Sep 2020 19:46:34
User entered 'No (N)'	System	12 Sep 2020 19:46:34

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:25', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '51e583ad-2b96-47b1-8082-dc9e85288403'	System	12 Sep 2020 19:46:34
User entered 'None (1)'	System	12 Sep 2020 19:46:34

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:31', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '51e583ad-2b96-47b1-8082-dc9e85288403'	System	12 Sep 2020 19:46:34
User entered '12 Sep 2020 15:46'	System	12 Sep 2020 19:46:34

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 6'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:55', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c40bf699-d550-44f7-9aae-a625bad7380e'	System	13 Sep 2020 23:25:15
User entered 'None (1)'	System	13 Sep 2020 23:25:15

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:24:58', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c40bf699-d550-44f7-9aae-a625bad7380e'	System	13 Sep 2020 23:25:15
User entered 'No (N)'	System	13 Sep 2020 23:25:15

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c40bf699-d550-44f7-9aae-a625bad7380e'	System	13 Sep 2020 23:25:15
User entered 'No (N)'	System	13 Sep 2020 23:25:15

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c40bf699-d550-44f7-9aae-a625bad7380e'	System	13 Sep 2020 23:25:15
User entered 'None (1)'	System	13 Sep 2020 23:25:15

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:11', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c40bf699-d550-44f7-9aae-a625bad7380e'	System	13 Sep 2020 23:25:15
User entered '13 Sep 2020 19:25'	System	13 Sep 2020 23:25:15

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 7'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:22', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3fb749cd-5429-4257-9734-3a872a64a65b'	System	14 Sep 2020 21:50:43
User entered 'None (1)'	System	14 Sep 2020 21:50:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3fb749cd-5429-4257-9734-3a872a64a65b'	System	14 Sep 2020 21:50:43
User entered 'No (N)'	System	14 Sep 2020 21:50:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3fb749cd-5429-4257-9734-3a872a64a65b'	System	14 Sep 2020 21:50:43
User entered 'No (N)'	System	14 Sep 2020 21:50:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3fb749cd-5429-4257-9734-3a872a64a65b'	System	14 Sep 2020 21:50:43
User entered 'None (1)'	System	14 Sep 2020 21:50:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3fb749cd-5429-4257-9734-3a872a64a65b'	System	14 Sep 2020 21:50:43
User entered '14 Sep 2020 17:50'	System	14 Sep 2020 21:50:43

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:44', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:27:57', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'None (0)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:28:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered 'No (N)'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T13:28:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6a8e975f-07d5-4be6-91c2-2ff866727d2f'	System	08 Sep 2020 17:28:09
User entered '08 Sep 2020 13:28'	System	08 Sep 2020 17:28:09

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 13:01'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 15:31'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:04', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'None (0)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:32', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered 'No (N)'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-08T18:02:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '19d989c0-ff8b-473f-b64e-5d52e25a0d00'	System	08 Sep 2020 22:02:46
User entered '08 Sep 2020 18:02'	System	08 Sep 2020 22:02:46

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '08 Sep 2020 16:26'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 2'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:52', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:56', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:20:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:21:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:21:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'None (0)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:21:13', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered 'No (N)'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-09T18:21:17', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c16578da-518e-4885-9aed-690108aadbe2'	System	09 Sep 2020 22:21:19
User entered '09 Sep 2020 18:21'	System	09 Sep 2020 22:21:19

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 3'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:01', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'None (0)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered 'No (N)'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-10T17:25:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '659d6278-7cf3-48ca-b90f-97550e71c47b'	System	10 Sep 2020 21:25:27
User entered '10 Sep 2020 17:25'	System	10 Sep 2020 21:25:27

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 4'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:53', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:11:57', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:12:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'None (0)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:12:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered 'No (N)'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-11T18:12:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '181fe850-62c2-43aa-805e-b730755600f1'	System	11 Sep 2020 22:12:24
User entered '11 Sep 2020 18:12'	System	11 Sep 2020 22:12:24

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 5'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:38', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:41', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:44', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:50', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'None (0)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:46:55', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered 'No (N)'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-12T15:47:01', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'bcd02fd0-28de-4ef1-a955-069e9cf8c791'	System	12 Sep 2020 19:47:04
User entered '12 Sep 2020 15:47'	System	12 Sep 2020 19:47:04

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 6'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:19', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:22', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:25', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:30', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:32', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:37', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'None (0)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:42', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered 'No (N)'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-13T19:25:49', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '000d5a7e-455d-461f-a043-cebbd10118fe'	System	13 Sep 2020 23:25:54
User entered '13 Sep 2020 19:25'	System	13 Sep 2020 23:25:54

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	08 Sep 2020 16:54:44
User entered 'Day 7'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:45', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:48', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:50', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:54', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:56', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:50:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'None (0)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:51:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered 'No (N)'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-09-14T17:51:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '95eae510-4082-46d0-ac81-e2dd3f4fc5e0'	System	14 Sep 2020 21:51:14
User entered '14 Sep 2020 17:51'	System	14 Sep 2020 21:51:14

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 16:54:44

US3352070

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:24

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 16:54:44

US3352070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Sep 2020 18:19:27

US3352070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '15 Sep 2020'	Yulexis Amestoy (b) (4)	15 Sep 2020 18:19:27

US3352070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	15 Sep 2020 18:19:27

US3352070

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Yulexis Amestoy (b) (4)	15 Sep 2020 18:19:27

US3352070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Sep 2020 18:19:32

US3352070

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'I'	System	15 Sep 2020 18:19:32

US3352070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:31:35

US3352070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 21:31:35

US3352070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 21:31:35

US3352070

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 21:31:35

US3352070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 21:31:40

US3352070

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'I'	System	22 Sep 2020 21:31:40

US3352070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	30 Sep 2020 15:26:17

US3352070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '30 Sep 2020'	Yulexis Amestoy (b) (4)	30 Sep 2020 15:26:17

US3352070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	30 Sep 2020 15:26:17

US3352070

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Yulexis Amestoy (b) (4)	30 Sep 2020 15:26:17

US3352070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	30 Sep 2020 15:26:25

US3352070

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'I'	System	30 Sep 2020 15:26:25

US3352070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 17:43:43

US3352070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:26:05
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:39:44
User entered '07 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:39:39
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 09:04:24
User entered '7 Oct 2020'	Matthew Muniz (b) (4)	07 Oct 2020 17:43:43

US3352070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	07 Oct 2020 17:43:43

US3352070

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'VISIT3'	System	07 Oct 2020 17:43:43

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:27:25
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	06 Nov 2020 15:10:05
User entered '07 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 15:10:01
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:26:13
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 17:57:00
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	07 Oct 2020 17:57:00
User entered '7 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 17:57:00
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	07 Oct 2020 17:56:39
User entered '6 Oct 2020'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:35'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered '07 Oct 2020 11:35'	System	06 Nov 2020 15:10:01
User entered '7 Oct 2020 11:35'	System	07 Oct 2020 17:57:00
User entered '6 Oct 2020 11:35'	System	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '36.8' C	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 19:29:27
Query 'Data is required. Please provide.' answered with 'not collected' (Site from System).	Matthew Muniz (b) (4)	07 Oct 2020 17:56:53
User opened query 'Data is required. Please provide.' System (Site from System).		07 Oct 2020 17:56:39
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered empty.	System	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '15'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'breaths/min'	System	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '108'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'mmHg'	System	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '67'	Matthew Muniz (b) (4)	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'mmHg'	System	07 Oct 2020 17:56:39

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:08:02

US3352070

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:24

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:08:02

US3352070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 17:57:07

US3352070

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:24

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 17:57:07

US3352070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 17:57:27

US3352070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '07 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 15:10:15
User entered '7 Oct 2020'	Matthew Muniz (b) (4)	07 Oct 2020 17:57:27

US3352070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '11:50'	Matthew Muniz (b) (4)	07 Oct 2020 17:57:27

US3352070

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered '07 Oct 2020 11:50'	System	06 Nov 2020 15:10:15
User entered '7 Oct 2020 11:50'	System	07 Oct 2020 17:57:27

US3352070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 17:57:37

US3352070

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:08:02
User entered 'I'	System	07 Oct 2020 17:57:37

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 64'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-17T08:59:28', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b974f4f6-136c-48d4-8d30-3eb0ec1c5546'	System	21 Oct 2020 15:18:59
User entered 'No (N)'	System	21 Oct 2020 15:18:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-17T08:59:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b974f4f6-136c-48d4-8d30-3eb0ec1c5546'	System	21 Oct 2020 15:18:59
User entered 'No (N)'	System	21 Oct 2020 15:18:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-17T08:59:45', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b974f4f6-136c-48d4-8d30-3eb0ec1c5546'	System	21 Oct 2020 15:18:59
User entered '17 Oct 2020 08:59:45'	System	21 Oct 2020 15:18:59

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 71'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-21T11:19:14', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b426cb02-4c83-4496-9a55-66d58bb5a296'	System	21 Oct 2020 15:19:28
User entered 'No (N)'	System	21 Oct 2020 15:19:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-21T11:19:19', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b426cb02-4c83-4496-9a55-66d58bb5a296'	System	21 Oct 2020 15:19:28
User entered 'No (N)'	System	21 Oct 2020 15:19:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-21T11:19:24', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b426cb02-4c83-4496-9a55-66d58bb5a296'	System	21 Oct 2020 15:19:28
User entered '21 Oct 2020 11:19:24'	System	21 Oct 2020 15:19:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 78'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-28T09:49:07', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '321b3393-a368-4611-840f-fd84935b3af3'	System	28 Oct 2020 13:49:24
User entered 'No (N)'	System	28 Oct 2020 13:49:24

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-28T09:49:13', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '321b3393-a368-4611-840f-fd84935b3af3'	System	28 Oct 2020 13:49:24
User entered 'No (N)'	System	28 Oct 2020 13:49:24

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-10-28T09:49:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '321b3393-a368-4611-840f-fd84935b3af3' User entered '28 Oct 2020 09:49:21'	System	28 Oct 2020 13:49:24
	System	28 Oct 2020 13:49:24

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 92'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-10T03:16:03', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'daab3eb2-42a6-4d0e-bbaa-327aa2863289'	System	10 Nov 2020 08:16:26
User entered 'No (N)'	System	10 Nov 2020 08:16:26

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-10T03:16:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'daab3eb2-42a6-4d0e-bbaa-327aa2863289'	System	10 Nov 2020 08:16:26
User entered 'No (N)'	System	10 Nov 2020 08:16:26

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-10T03:16:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'daab3eb2-42a6-4d0e-bbaa-327aa2863289' User entered '10 Nov 2020 03:16:21'	System	10 Nov 2020 08:16:26
	System	10 Nov 2020 08:16:26

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered 'Day 99'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-17T00:02:13', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'efece921-d897-4224-ba1a-ffa390ab236f'	System	17 Nov 2020 05:02:28
User entered 'No (N)'	System	17 Nov 2020 05:02:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-17T00:02:18', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'efece921-d897-4224-ba1a-ffa390ab236f'	System	17 Nov 2020 05:02:28
User entered 'No (N)'	System	17 Nov 2020 05:02:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-17T00:02:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'efece921-d897-4224-ba1a-ffa390ab236f' User entered '17 Nov 2020 00:02:26'	System	17 Nov 2020 05:02:28
	System	17 Nov 2020 05:02:28

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 17:22:33

US3352070

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:20:24
Data entry locked.	System	13 Aug 2020 17:22:33
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 17:22:33

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2020-11-25T10:05:02', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '70b298d0-845e-43c8-9fb4-7ad6b974ef00'	System	25 Nov 2020 15:06:38
User entered 'No (N)'	System	25 Nov 2020 15:06:38

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2020-11-25T10:04:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '70b298d0-845e-43c8-9fb4-7ad6b974ef00'	System	25 Nov 2020 15:06:38
User entered 'No (N)'	System	25 Nov 2020 15:06:38

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Please 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)
DataPoint set to visible.	System	25 Nov 2020 15:06:38
DataPoint set to invisible.	System	25 Nov 2020 15:06:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-25T10:06:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '70b298d0-845e-43c8-9fb4-7ad6b974ef00'	System	25 Nov 2020 15:06:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 15:06:38

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-11-25T10:06:28', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '70b298d0-845e-43c8-9fb4-7ad6b974ef00'	System	25 Nov 2020 15:06:38
User entered '25 Nov 2020 10:06:28'	System	25 Nov 2020 15:06:38

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2020-12-09T11:24:26', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3b37192f-299f-4600-a720-2a0fbdc50e9d'	System	09 Dec 2020 16:25:46
User entered 'No (N)'	System	09 Dec 2020 16:25:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2020-12-09T11:24:28', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3b37192f-299f-4600-a720-2a0fbdc50e9d'	System	09 Dec 2020 16:25:46
User entered 'No (N)'	System	09 Dec 2020 16:25:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-12-09T11:25:42', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '3b37192f-299f-4600-a720-2a0fbdc50e9d' User entered '09 Dec 2020 11:25:42'	System	09 Dec 2020 16:25:46
	System	09 Dec 2020 16:25:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2020-12-12T07:21:19', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2c670c4a-444e-4049-a693-955415566681'	System	12 Dec 2020 12:22:17
User entered 'No (N)'	System	12 Dec 2020 12:22:17

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2020-12-12T07:21:24', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2c670c4a-444e-4049-a693-955415566681'	System	12 Dec 2020 12:22:17
User entered 'No (N)'	System	12 Dec 2020 12:22:17

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-12-12T07:22:12', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '2c670c4a-444e-4049-a693-955415566681' User entered '12 Dec 2020 07:22:12'	System	12 Dec 2020 12:22:17
	System	12 Dec 2020 12:22:17

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2020-12-20T10:02:47', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4321fa45-96b2-4de4-805a-b028226ea68a'	System	20 Dec 2020 15:03:47
User entered 'No (N)'	System	20 Dec 2020 15:03:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2020-12-20T10:02:51', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4321fa45-96b2-4de4-805a-b028226ea68a'	System	20 Dec 2020 15:03:47
User entered 'No (N)'	System	20 Dec 2020 15:03:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-12-20T10:03:42', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4321fa45-96b2-4de4-805a-b028226ea68a' User entered '20 Dec 2020 10:03:42'	System	20 Dec 2020 15:03:47
	System	20 Dec 2020 15:03:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2020-12-29T16:13:05', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '07e8de30-60f3-4bd8-8056-e15062b41308'	System	29 Dec 2020 21:13:46
User entered 'No (N)'	System	29 Dec 2020 21:13:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2020-12-29T16:13:09', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '07e8de30-60f3-4bd8-8056-e15062b41308'	System	29 Dec 2020 21:13:46
User entered 'No (N)'	System	29 Dec 2020 21:13:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2020-12-29T16:13:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '07e8de30-60f3-4bd8-8056-e15062b41308' User entered '29 Dec 2020 16:13:40'	System	29 Dec 2020 21:13:46
	System	29 Dec 2020 21:13:46

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-01-11T09:10:40', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4a058c1b-cbe9-47be-a8c3-5e6f3dcd1f3c'	System	12 Jan 2021 18:30:28
User entered 'No (N)'	System	12 Jan 2021 18:30:28

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-01-12T13:30:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4a058c1b-cbe9-47be-a8c3-5e6f3dcd1f3c'	System	12 Jan 2021 18:30:28
User entered 'No (N)'	System	12 Jan 2021 18:30:28

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-01-12T13:30:22', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '4a058c1b-cbe9-47be-a8c3-5e6f3dcd1f3c'	System	12 Jan 2021 18:30:28
User entered '12 Jan 2021 13:30:22'	System	12 Jan 2021 18:30:28

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-01-20T07:37:06', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6d3ced95-7246-469c-bdcc-d7fc80ce4869'	System	20 Jan 2021 12:37:18
User entered 'No (N)'	System	20 Jan 2021 12:37:18

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-01-20T07:37:10', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6d3ced95-7246-469c-bdcc-d7fc80ce4869'	System	20 Jan 2021 12:37:18
User entered 'No (N)'	System	20 Jan 2021 12:37:18

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-01-20T07:37:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '6d3ced95-7246-469c-bdcc-d7fc80ce4869' User entered '20 Jan 2021 07:37:15'	System	20 Jan 2021 12:37:18
	System	20 Jan 2021 12:37:18

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-01-25T10:00:16', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a1ecdb2a-877f-41ea-90d8-b4ee60aed03d'	System	25 Jan 2021 15:00:30
User entered 'No (N)'	System	25 Jan 2021 15:00:30

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-01-25T10:00:20', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a1ecdb2a-877f-41ea-90d8-b4ee60aed03d'	System	25 Jan 2021 15:00:30
User entered 'No (N)'	System	25 Jan 2021 15:00:30

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-01-25T10:00:24', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a1ecdb2a-877f-41ea-90d8-b4ee60aed03d' User entered '25 Jan 2021 10:00:24'	System	25 Jan 2021 15:00:30
	System	25 Jan 2021 15:00:30

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-02-03T16:17:11', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16559699-2ff7-42d7-9899-9c0593a721ce'	System	03 Feb 2021 21:17:26
User entered 'No (N)'	System	03 Feb 2021 21:17:26

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-02-03T16:17:15', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16559699-2ff7-42d7-9899-9c0593a721ce'	System	03 Feb 2021 21:17:26
User entered 'No (N)'	System	03 Feb 2021 21:17:26

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-02-03T16:17:21', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '16559699-2ff7-42d7-9899-9c0593a721ce'	System	03 Feb 2021 21:17:26
User entered '03 Feb 2021 16:17:21'	System	03 Feb 2021 21:17:26

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-02-09T10:54:53', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3d1e240-75bc-420a-b5d7-a129c0307cce'	System	09 Feb 2021 15:55:04
User entered 'No (N)'	System	09 Feb 2021 15:55:04

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-02-09T10:54:56', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3d1e240-75bc-420a-b5d7-a129c0307cce'	System	09 Feb 2021 15:55:04
User entered 'No (N)'	System	09 Feb 2021 15:55:04

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-02-09T10:54:59', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'e3d1e240-75bc-420a-b5d7-a129c0307cce'	System	09 Feb 2021 15:55:04
User entered '09 Feb 2021 10:54:59'	System	09 Feb 2021 15:55:04

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-02-27T16:27:18', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '68aca086-d658-4e78-a1d3-aa3d22be05a0'	System	27 Feb 2021 21:27:34
User entered 'No (N)'	System	27 Feb 2021 21:27:34

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-02-27T16:27:23', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '68aca086-d658-4e78-a1d3-aa3d22be05a0'	System	27 Feb 2021 21:27:34
User entered 'No (N)'	System	27 Feb 2021 21:27:34

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-02-27T16:27:27', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '68aca086-d658-4e78-a1d3-aa3d22be05a0'	System	27 Feb 2021 21:27:34
User entered '27 Feb 2021 16:27:27'	System	27 Feb 2021 21:27:34

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-03-09T16:25:34', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c39f44b9-997d-4ad2-8a7b-9b1e2156ca02'	System	09 Mar 2021 21:25:50
User entered 'No (N)'	System	09 Mar 2021 21:25:50

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-03-09T16:25:39', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c39f44b9-997d-4ad2-8a7b-9b1e2156ca02'	System	09 Mar 2021 21:25:50
User entered 'No (N)'	System	09 Mar 2021 21:25:50

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-03-09T16:25:44', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c39f44b9-997d-4ad2-8a7b-9b1e2156ca02' User entered '09 Mar 2021 16:25:44'	System	09 Mar 2021 21:25:50
	System	09 Mar 2021 21:25:50

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-03-17T11:57:29-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a395609b-cbf6-4332-901a-badd72fe531d'	System	17 Mar 2021 15:57:45
User entered 'No (N)'	System	17 Mar 2021 15:57:45

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-03-17T11:57:34-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a395609b-cbf6-4332-901a-badd72fe531d'	System	17 Mar 2021 15:57:45
User entered 'No (N)'	System	17 Mar 2021 15:57:45

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-03-17T11:57:39-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'a395609b-cbf6-4332-901a-badd72fe531d'	System	17 Mar 2021 15:57:45
User entered '17 Mar 2021 11:57:39'	System	17 Mar 2021 15:57:45

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-03-20T18:02:23-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c4875fca-5ba1-41e9-a9ad-7fbf171f7073'	System	20 Mar 2021 22:06:25
User entered 'No (N)'	System	20 Mar 2021 22:06:25

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-03-20T18:02:29-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c4875fca-5ba1-41e9-a9ad-7fbf171f7073'	System	20 Mar 2021 22:06:25
User entered 'No (N)'	System	20 Mar 2021 22:06:25

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-03-20T18:02:38-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'c4875fca-5ba1-41e9-a9ad-7fbf171f7073' User entered '20 Mar 2021 18:02:38'	System	20 Mar 2021 22:06:25

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-03-31T02:03:03-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b8ba5016-589a-4cb4-a649-e7b33bdd6d51'	System	31 Mar 2021 06:03:16
User entered 'No (N)'	System	31 Mar 2021 06:03:16

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-03-31T02:03:06-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b8ba5016-589a-4cb4-a649-e7b33bdd6d51'	System	31 Mar 2021 06:03:16
User entered 'No (N)'	System	31 Mar 2021 06:03:16

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-03-31T02:03:13-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'b8ba5016-589a-4cb4-a649-e7b33bdd6d51'	System	31 Mar 2021 06:03:16
User entered '31 Mar 2021 02:03:13'	System	31 Mar 2021 06:03:16

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-04-06T09:24:51-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dac1e585-39a8-48cd-a3b0-4b86556fe4dc' User entered 'No (N)'	System	06 Apr 2021 13:25:14
	System	06 Apr 2021 13:25:14

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-04-06T09:24:58-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dac1e585-39a8-48cd-a3b0-4b86556fe4dc'	System	06 Apr 2021 13:25:14
User entered 'No (N)'	System	06 Apr 2021 13:25:14

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-04-06T09:25:08-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: 'dac1e585-39a8-48cd-a3b0-4b86556fe4dc'	System	06 Apr 2021 13:25:14
User entered '06 Apr 2021 09:25:08'	System	06 Apr 2021 13:25:14

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-04-14T11:47:58-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '037bf68d-9edc-41c5-852a-9b764ca5c2f6'	System	14 Apr 2021 15:49:54
User entered 'No (N)'	System	14 Apr 2021 15:49:54

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-04-14T11:48:06-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '037bf68d-9edc-41c5-852a-9b764ca5c2f6'	System	14 Apr 2021 15:49:54
User entered 'No (N)'	System	14 Apr 2021 15:49:54

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-04-14T11:48:12-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '037bf68d-9edc-41c5-852a-9b764ca5c2f6'	System	14 Apr 2021 15:49:54
User entered '14 Apr 2021 11:48:12'	System	14 Apr 2021 15:49:54

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[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 (c6a846973f1cc0d3)', Time: '2021-04-19T10:39:35-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7e2b82fb-3be5-43ac-92ce-7f55275bea46'	System	19 Apr 2021 14:39:47
User entered 'No (N)'	System	19 Apr 2021 14:39:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

Have you been exposed to someone with 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 (c6a846973f1cc0d3)', Time: '2021-04-19T10:39:39-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7e2b82fb-3be5-43ac-92ce-7f55275bea46'	System	19 Apr 2021 14:39:47
User entered 'No (N)'	System	19 Apr 2021 14:39:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-04-19T10:39:43-04:00', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '7e2b82fb-3be5-43ac-92ce-7f55275bea46'	System	19 Apr 2021 14:39:47
User entered '19 Apr 2021 10:39:43'	System	19 Apr 2021 14:39:47

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:07:52

US3352070

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:24

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:07:52
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:07:52

US3352070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:24

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)	26 Apr 2021 05:23:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-02-27T16:27:36', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '50dda6ec-c5b9-4e5a-96a5-bb7a2d5b21f2'	System	27 Feb 2021 21:27:42
User entered 'No (N)'	System	27 Feb 2021 21:27:42

US3352070

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:24

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:23:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c6a846973f1cc0d3)', Time: '2021-02-27T16:27:39', User OID: 'PatientReportedOutcome (US3352070)', ODM File OID: '50dda6ec-c5b9-4e5a-96a5-bb7a2d5b21f2'	System	27 Feb 2021 21:27:42
User entered '27 Feb 2021 16:27:39'	System	27 Feb 2021 21:27:42

US3352070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 19:29:37

US3352070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered '2 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 19:29:37

US3352070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Nov 2020 19:29:37

US3352070

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 19:29:37

US3352070

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:34:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 19:29:41

US3352070

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:50
User entered 'I'	System	02 Nov 2020 19:29:41

US3352070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 19:52:58

US3352070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '9 Dec 2020'	(b) (4), (b) (6)	09 Dec 2020 19:52:58

US3352070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Dec 2020 19:52:58

US3352070

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 19:52:58

US3352070

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 19:53:01

US3352070

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User entered 'I'	System	09 Dec 2020 19:53:01

US3352070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:28:00

US3352070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '4 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 17:28:00

US3352070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Jan 2021 17:28:00

US3352070

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'MULTIPLE ATTEMPTS, NO ANSWER'	(b) (4), (b) (6)	28 Jan 2021 17:28:00

US3352070

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 17:28:07

US3352070

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User entered 'I'	System	28 Jan 2021 17:28:07

US3352070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	Sara Gomez (b) (4)	27 Mar 2021 14:12:25

US3352070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Mar 2021 14:12:44
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	27 Mar 2021 14:12:44
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	27 Mar 2021 14:12:44
User entered '04 Feb 2021' reason for change: Data Entry Error	Sara Gomez (b) (4)	27 Mar 2021 14:12:44
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	27 Mar 2021 14:12:25
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	27 Mar 2021 14:12:25
User entered '04 Apr 2021'	Sara Gomez (b) (4)	27 Mar 2021 14:12:25

US3352070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	27 Mar 2021 16:50:29
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4)	27 Mar 2021 14:12:25

US3352070

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:24

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Unable to get in contact with subject.'	Rosaidaliz Carreira (b) (4)	27 Mar 2021 16:50:29
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Sara Gomez (b) (4)	27 Mar 2021 14:12:25
	(b) (4)	

US3352070

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 11:34:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	27 Mar 2021 14:18:13
Query 'Data is required. Please complete.' answered with 'NO DONE' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Sara Gomez (b) (4)	27 Mar 2021 14:18:02
User entered empty; reason for change Data Entry Error	System	27 Mar 2021 14:17:51
User entered 'Yes (Y)'	Sara Gomez (b) (4)	27 Mar 2021 14:17:51
	(b) (4)	
	Sara Gomez (b) (4)	27 Mar 2021 14:12:07
	(b) (4)	

US3352070

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:24

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:31:46
User entered '1'	System	27 Mar 2021 14:18:13
User entered empty.	System	27 Mar 2021 14:17:51
User entered '1'	System	27 Mar 2021 14:12:07

US3352070

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:58
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 19:31:48

US3352070

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:58
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 19:31:48

US3352070

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:58
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Jan 2021 19:31:48

US3352070

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:24

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:31:58
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered 'UNBLND_DECIDE'	System	16 Jan 2021 19:31:48

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '0'	(b) (4), (b) (6)	30 Mar 2021 22:21:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:08

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	30 Mar 2021 22:21:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:43:08

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:50:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:50:46
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'No (N)'	(b) (4), (b) (6)	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	16 Jan 2021 19:36:13

US3352070

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:24

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:02
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered empty.	System	16 Jan 2021 19:36:13

US3352070

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 19:37:24

US3352070

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 19:37:24

US3352070

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '14:00'	(b) (4), (b) (6)	16 Jan 2021 19:37:24

US3352070

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:24

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '16 Jan 2021 14:00'	System	16 Jan 2021 19:37:24

US3352070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:24

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Jan 2021 19:37:41

US3352070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:24

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '16 Jan 2021'	(b) (4), (b) (6)	16 Jan 2021 19:37:41

US3352070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:24

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '13:50'	(b) (4), (b) (6)	16 Jan 2021 19:37:41

US3352070

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:24

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:49:36
Data hard unlocked.	(b) (4), (b) (6)	27 Apr 2021 15:32:08
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:29:06
User entered '16 Jan 2021 13:50'	System	16 Jan 2021 19:37:41

US3352070

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:10:24

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:23:14
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 17:59:42

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Tibia fracture, LLT: Tibia fracture - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:30:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Oct 2020 00:30:18
Data point term sent to Coder	System	07 Oct 2020 18:08:31
User entered 'left distal tibia fracture'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '25 Sep 2020'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 14:12:06
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'correct as entered ' (Site from System).	Matthew Muniz (b) (4)	07 Oct 2020 18:09:13
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Oct 2020 18:07:57
User entered '11:00'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:00'	System	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 05:16:04
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 'AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 18:29:36
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)	27 Nov 2020 10:24:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 18:12:44
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 18:12:44
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 18:07:57
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:12:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 18:12:31
User entered 'None (NONE)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 18:12:31
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 18:07:57
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 14:53:01
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Oct 2020 18:13:17
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 18:13:17
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	07 Oct 2020 18:07:57
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Per CDM: "Concomitant Medication" is not checked, however a Medication with the Indication of "Tibia fracture" and a start date of 25SEP2020 has been added. Please review and consider updating this field or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:32:01
Query 'Per CDM: "Concomitant Medication" is not checked, however a Medication with the Indication of "Tibia fracture" and a start date of 25SEP2020 has been added. Please review and consider updating this field or comment accordingly. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:53:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 14:53:01
User opened query 'Per CDM: "Concomitant Medication" is not checked, however a Medication with the Indication of "Tibia fracture" and a start date of 25SEP2020 has been added. Please review and consider updating this field or comment accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 15:49:06
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 18:07:57

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:16:27
User entered 'USA-US066-2021-mRNA-1273-P301000008'	System	24 Mar 2021 13:16:22
User entered 'New'	(b) (4), (b) (6)	24 Mar 2021 13:16:22

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 04:53:27
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Unable to get in contact with subject ' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	19 Apr 2021 17:35:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:10:18
User closed query 'Per DM CLR: Please note the start date of this AE overlaps with AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:10:18
Query 'Per DM CLR: Please note the start date of this AE overlaps with AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' answered with 'Pending curent health status to update' (Site from DM).	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:34:06
User opened query 'Per DM CLR: Please note the start date of this AE overlaps with AE #1. Please note that any sequential AE that fluctuates in severity during the course of the study should be reported once at the highest severity observed with the start/stop dates aslo reconciled. Review and update AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:15:52

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Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Tibia fracture, LLT: Tibia fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:29:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:29:30
Data point term sent to Coder	System	23 Mar 2021 18:07:15
User entered 'Worsening of left distal tibia fracture'	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021' reason for change: New Information	Surisaday Mederos (b) (4)	12 Apr 2021 16:56:57
User entered '13 Mar 2021'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:06:35

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:51:33
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:09:14
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' answered with 'Pending current health status, subjects does not answer the phone. ' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 16:34:56
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:11:42
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Generated On: 09 Jun 2021 17:10:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:09
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Unable to get in contact with subject.' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:35:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:15:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 21:51:13
DataPoint Verified.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Grade 4 (Grade 4)'	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 03:57:35
User closed query 'Per CDM-Response noted,however,kindly consider to update data when available.Please eave this query open until resolution.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 03:57:33
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Unable to get in contact with subject to update status' (Site from System).	Surisaday Mederos (b) (4)	19 Apr 2021 17:36:58
Query 'Per CDM-Response noted,however,kindly consider to update data when available.Please eave this query open until resolution.' answered with 'Unable to get in contact with subject' (Site from DM).	Surisaday Mederos (b) (4)	19 Apr 2021 17:36:05
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Apr 2021 16:57:19
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 06:49:51
User opened query 'Per CDM-Response noted,however,kindly consider to update data when available.Please eave this query open until resolution.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:49:47

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Folder: Adverse Events

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Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is at the hospital medical records requested - ' (Site from System).	Sara Gomez (b) (4)	27 Mar 2021 14:24:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User 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	27 Mar 2021 14:23:28
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 07:05:47
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is currently hospitalized.' (Site from System).	Surisaday Mederos (b) (4)	23 Mar 2021 18:08:32
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User 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	23 Mar 2021 18:06:35
User entered 'I'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Unable to obtain this information. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:12
DataPoint Verified.	Surisaday Mederos (b) (4)	19 Apr 2021 17:37:58
User entered '10 Mar 2021' reason for change: New Information	(b) (4)	14 Apr 2021 17:17:59
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 16:57:19
User entered '13 Mar 2021'	(b) (4), (b) (6)	02 Apr 2021 23:12:48
		23 Mar 2021 18:06:35

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:14
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Unable to get in contact with subject.' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:38:15
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:14:22
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:09:21
Query 'PV Query: Please provide the hospital discharge date when available. ' answered with 'Subject was still hospitalized unable to get in contact with subject recently.' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 16:45:01
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:12:55
User entered empty.	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Per CDM Requery-Response noted,however,kindy consider to update confirmed data when available.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:13:33
Query 'Per CDM Requery-Response noted,however,kindy consider to update confirmed data when available.' answered with 'Aooording to medical recrods received, subject was not admitted to ICU.' (Site from DM).	Surisaday Mederos (b) (4)	12 Apr 2021 16:45:44
User opened query 'Per CDM Requery-Response noted,however,kindy consider to update confirmed data when available.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:50:58
User closed query 'Per CDM-Response noted as 'Pending medical records to confirm ICU status,however,Kindly consider to update data to 'Yes/No',when data is available.Please eave this query open until resolution.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:50:58
Query 'Per CDM-Response noted as 'Pending medical records to confirm ICU status,however,Kindly consider to update data to 'Yes/No',when data is available.Please eave this query open until resolution.' answered with 'This info will be confirmed with Investigator.' (Site from DM).	Sara Gomez (b) (4)	27 Mar 2021 14:24:37
User entered 'No (N)' reason for change: Data Entry Error	Sara Gomez (b) (4)	27 Mar 2021 14:24:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Gomez (b) (4)	27 Mar 2021 14:23:28
User opened query 'Per CDM-Response noted as 'Pending medical records to confirm ICU status,however,Kindly consider to update data to 'Yes/No',when data is available.Please eave this query open until resolution.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:07:42
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 08:03:56

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending medical records to confirm ICU status.' (Site from System).	Surisaday Mederos (b) (4)	23 Mar 2021 18:09:07
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Mar 2021 18:06:35
User entered 'Unknown (UNK)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Mar 2021 06:52:29
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'Subject is at the hospital medical records requested - ' (Site from System).	Sara Gomez (b) (4) (b) (4)	27 Mar 2021 14:23:57
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	27 Mar 2021 14:23:28
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	23 Mar 2021 18:06:35

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None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'PV Query: Please specify the antibiotics given to the subject for the treatment of the event. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:09:24
Query 'PV Query: Please specify the antibiotics given to the subject for the treatment of the event. ' answered with 'Medications listed were entered already. ' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 16:46:48
User opened query 'PV Query: Please specify the antibiotics given to the subject for the treatment of the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:11:56
User entered 'I'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:17
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Unable to get in contact with subject.' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:38:31
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:14:58
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 16:09:27
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Unable to get in contact with subject, does not answer the phone.' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 17:05:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:12:17
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[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. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:51:48
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:51:41
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'PV QUERY: Please clarify the indication for medication 'acetaminophen HCL structure oxycodone'. ' (Site from Safety).		13 Apr 2021 16:09:36
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).		13 Apr 2021 16:09:35
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		13 Apr 2021 16:09:33
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).		13 Apr 2021 16:09:30
User closed query 'Per DM CLR: Narrative = IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:20:14
User closed query 'Per DM CLR: Narrative = RECONSTRUCTIVE SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 14:18:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with ' Hematology significant for (3/10/201)WBC 21.84 UL (referene range 4.00-11.00). ' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 17:39:12
Query 'PV QUERY: Please clarify the indication for medication 'acetaminophen HCL structure oxycodone'. ' answered with 'Associated with adverse events reported.' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 17:04:31
Query 'Per DM CLR: Narrative = IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Maxipime/ sodoium chloride 0.9 % 50 ml PB.' (Site from DM).	Surisaday Mederos (b) (4)	12 Apr 2021 17:02:55
Query 'Per DM CLR: Narrative = RECONSTRUCTIVE SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Concomitant procedure page was update. ' (Site from DM).	Surisaday Mederos (b) (4)	12 Apr 2021 17:01:22
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Subject with a previous left distal tibia fracture since 9/30/2020.' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 16:59:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Covid 19 test performed 10 March 2021: Negative' (Site from Safety).	Surisaday Mederos (b) (4)	12 Apr 2021 16:47:33
User opened query 'Per DM CLR: Narrative = IV ANTIBIOTICS. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:15:45
User opened query 'Per DM CLR: Narrative = RECONSTRUCTIVE SURGERY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:15:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV QUERY: Please clarify the indication for medication 'acetaminophen HCL structure oxycodone'.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 23:12:38
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).		02 Apr 2021 23:12:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		02 Apr 2021 23:12:24
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).		02 Apr 2021 23:12:05
User entered 'Subject reported having reconstructive surgery for previous fracture of left distal tibia. He is being hospitalized since 13 March 2021. He reported that he is receiving IV antibiotics. He does not know when he is going to be discharge. He denies having Covid 19 symptms. Medical records will be requested to include details of the event including treatment.'	Surisaday Mederos (b) (4)	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 18:06:35

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 18:06:35

US3352070

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
User entered '0'	System	27 Mar 2021 14:24:15
User entered '1'	System	27 Mar 2021 14:23:28
User entered '0'	System	23 Mar 2021 18:06:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
Reviewed for Safety.		12 Apr 2021 13:16:38
User entered 'USA-US066-2021-mRNA-1273-P301000008'		12 Apr 2021 13:16:24

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Popliteal vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:21:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:21:32
Data point term sent to Coder	System	09 Apr 2021 18:20:16
User entered 'Left Popliteal Deep Vein Thrombosis'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Unable to get in contact with subject' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:43:18
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:17:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Grade 4 (Grade 4)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 07:03:09
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending information for hospitalization discharge, subject does not answer the phone.' (Site from System).	Surisaday Mederos (b) (4)	09 Apr 2021 18:21:45
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:20:13
User entered 'I'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:20:13

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'I'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:33:37
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Unable to get in contact with subject.' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:43:44
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:18:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Medical Records obtained from the hospital revealed that subject presented to the Emergency Department complaining of left lower leg pain, swelling, redness and drainage. Also reported shortness of breath and subjective fever. Subject with a history of left distal tibia fracture. Upon further evaluation and testing he was admitted to the hospital with a left popliteal deep vein thrombosis, sepsis and cellulitis of his right leg. Pending to obtain more information about current hospitalization status.'	Surisaday Mederos (b) (4)	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 18:20:13

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:18:09
User entered 'USA-US066-2021-mRNA-1273-P301000008'	(b) (4), (b) (6)	12 Apr 2021 13:18:04

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:04:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:04:54
Data point term sent to Coder	System	22 Apr 2021 17:04:06
DataPoint Un-verified.	Surisaday Mederos (b) (4)	22 Apr 2021 17:03:38
Coding entries removed.	Surisaday Mederos (b) (4)	22 Apr 2021 17:03:38
User entered 'CELLULITIS OF LEFT LEG' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	22 Apr 2021 17:03:38
User closed query 'PV Query: Please reassess the event "cellulitis of right leg" and please confirm if cellulitis was at the right or left leg.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:32:32
Query 'PV Query: Please reassess the event "cellulitis of right leg" and please confirm if cellulitis was at the right or left leg.' answered with 'Medical records page 7 out of 63 reports "Cellulitis of right leg".' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:51:57
User opened query 'PV Query: Please reassess the event "cellulitis of right leg" and please confirm if cellulitis was at the right or left leg.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:09:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of leg - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:13:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Apr 2021 19:13:41
Data point term sent to Coder	System	09 Apr 2021 18:24:21
User entered 'Cellulitis of right leg'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '5 Apr 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Pending status about resolution if applicable. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:32:39
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:56:03
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:08:56
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Grade 4 (Grade 4)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
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	09 Apr 2021 18:25:10
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	09 Apr 2021 18:24:09
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 07:08:45
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Unknown current hospitalization status.' (Site from System).	Surisaday Mederos (b) (4)	09 Apr 2021 18:25:44
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	09 Apr 2021 18:25:10
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	09 Apr 2021 18:25:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:25:10
User entered '1' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	09 Apr 2021 18:25:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	09 Apr 2021 18:24:09
User entered '0'	System	09 Apr 2021 18:24:09
	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6) Surisaday Mederos (b) (4) (b) (4)	20 Apr 2021 19:32:43 19 Apr 2021 17:57:33
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	19 Apr 2021 17:57:12
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:09:07 14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6) Surisaday Mederos (b) (4) (b) (4)	20 Apr 2021 19:32:45 19 Apr 2021 17:58:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	19 Apr 2021 17:58:16
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:09:10 14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'I'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:32:47
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Pending outcome status. ' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 17:58:47
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:09:35
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'MEDICAL RECORDS OBTAINED FROM THE HOSPITAL REVEALED THAT SUBJECT PRESENTED TO THE EMERGENCY DEPARTMENT COMPLAINING OF LEFT LOWER LEG PAIN, SWELLING, REDNESS AND DRAINAGE. ALSO REPORTED SHORTNESS OF BREATH AND SUBJECTIVE FEVER. SUBJECT WITH A HISTORY OF LEFT DISTAL TIBIA FRACTURE. UPON FURTHER EVALUATION AND TESTING HE WAS ADMITTED TO THE HOSPITAL WITH A LEFT POPLITEAL DEEP VEIN THROMBOSIS, SEPSIS AND CELLULITIS OF HIS RIGHT LEG. PENDING TO OBTAIN MORE INFORMATION ABOUT CURRENT HOSPITALIZATION STATUS.'	Surisaday Mederos (b) (4)	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:24:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 18:24:09

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
Reviewed for Safety.		12 Apr 2021 13:18:57
User entered 'USA-US066-2021-mRNA-1273-P301000008'		12 Apr 2021 13:18:53

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:28:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Apr 2021 18:28:55
Data point term sent to Coder	System	09 Apr 2021 18:27:23
User entered 'Sepsis'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:56:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Subject was confirmed to be still hospitalized. ' (Site from Safety).	Surisaday Mederos (b) (4)	22 Apr 2021 16:45:25
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:10:47
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Grade 4 (Grade 4)' reason for change:	Surisaday Mederos (b) (4)	09 Apr 2021 18:28:36
Data Entry Error	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	09 Apr 2021 18:28:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	09 Apr 2021 18:28:36
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	09 Apr 2021 18:27:14
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 07:08:54
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Unknown current hospitalization status.' (Site from System).	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:45
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Apr 2021 18:27:14
User entered 'I'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'No (N)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:56:31
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated' (Site from Safety).	Surisaday Mederos (b) (4)	22 Apr 2021 16:43:28
DataPoint Un-verified.	Surisaday Mederos (b) (4)	22 Apr 2021 16:41:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	22 Apr 2021 16:41:51
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:11:45
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:56:35
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated' (Site from Safety).	Surisaday Mederos (b) (4)	22 Apr 2021 16:43:38
DataPoint Un-verified.	Surisaday Mederos (b) (4)	22 Apr 2021 16:41:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	22 Apr 2021 16:41:51
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:12:07
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'I'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered '0'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:56:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject is currently hospitalized. ' (Site from Safety).	Surisaday Mederos (b) (4)	22 Apr 2021 16:57:14
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 16:10:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4)	09 Apr 2021 18:27:14
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:17:59
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 18:28:36
User entered '0'	System	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 18:27:14

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:21:24
User entered 'USA-US066-2021-mRNA-1273-P301000011'	System	15 Apr 2021 13:21:17
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 13:21:17

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Wound infection, LLT: Wound infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 17:54:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 17:54:58
Data point term sent to Coder	System	14 Apr 2021 17:53:49
User entered 'Wound Infection'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '20 Dec 2020'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:53:35

US3352070

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	30 Apr 2021 16:57:38
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Event still ongoing. ' (Site from Safety).	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	Surisaday Mederos (b) (4)	27 Apr 2021 17:06:34
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 14:53:02
	(b) (4), (b) (6)	14 Apr 2021 19:05:44
	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Grade 4 (Grade 4)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
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	14 Apr 2021 17:54:30
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	14 Apr 2021 17:53:35
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:35:42
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Admitted to ICU is unknown, discharged date is unknown. ' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 19:05:44
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).	Surisaday Mederos (b) (4)	14 Apr 2021 17:55:22
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).	(b) (4)	14 Apr 2021 17:54:30
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	14 Apr 2021 17:54:30
User entered '1' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 17:54:30
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	14 Apr 2021 17:53:35
User entered '0'	System	14 Apr 2021 17:53:35
	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '20 Dec 2020'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:57:49
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'No discharge documents available. Subject hospitalized. ' (Site from Safety).	Surisaday Mederos (b) (4)	27 Apr 2021 17:21:34
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:52:02
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 12:35:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'Pending medical records. ' (Site from System).	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:55:45
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	14 Apr 2021 17:53:35
User entered 'Unknown (UNK)'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Howard schwartz (b) (4)	30 Apr 2021 16:57:55 28 Apr 2021 11:04:43
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated ' (Site from Safety). DataPoint Un-verified.	Surisaday Mederos (b) (4) (b) (4) Surisaday Mederos (b) (4) (b) (4)	27 Apr 2021 17:23:31 27 Apr 2021 17:23:02 27 Apr 2021 17:23:02
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Apr 2021 14:51:41 14 Apr 2021 19:05:44
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Un-verified.	Surisaday Mederos (b) (4)	27 Apr 2021 17:28:44
User entered 'Not Related (NOT RELATED)'	(b) (4)	27 Apr 2021 17:28:44
reason for change: Data Entry Error	Surisaday Mederos (b) (4)	27 Apr 2021 17:28:44
DataPoint Verified.	(b) (4)	14 Apr 2021 19:05:44
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Apr 2021 19:05:44
	(b) (4)	14 Apr 2021 17:53:35
	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'I'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:16
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Pending to receive medical records.' (Site from Safety).	Surisaday Mederos (b) (4)	27 Apr 2021 17:30:56
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:53:36
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:53:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 16:58:25
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) (6)	30 Apr 2021 16:58:22
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)	30 Apr 2021 16:58:19
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 11:04:43
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Pending to receive medical records. ' (Site from Safety).	Surisaday Mederos (b) (4)	27 Apr 2021 17:30:20

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Pending medical records for this incident. ' (Site from Safety).	Surisaday Mederos (b) (4)	(b) (4) 27 Apr 2021 17:29:57
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 'No medical records. Pending to receive at site. ' (Site from Safety).	Surisaday Mederos (b) (4)	(b) (4) 27 Apr 2021 17:29:30
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 submit when available.' (Site from Safety).	Surisaday Mederos (b) (4)	(b) (4) 27 Apr 2021 17:25:37
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:53:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:53:22

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Folder: Adverse Events

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[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 or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:52:20
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)	23 Apr 2021 14:51:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:05:44
User entered 'Information obtained from medical records. Antibiotics listed but no name of medications are provided.'	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 17:53:35

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 17:53:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
User entered '0'	System	14 Apr 2021 17:53:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:10:24

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User closed query 'Per ETRTR: According to SAE page "Worsening of Left Distal Tibia Fracture", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:40:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:40:04
Query 'Per ETRTR: According to SAE page "Worsening of Left Distal Tibia Fracture", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' answered with 'Medications will be entered' (Site from CRA).	Surisaday Mederos (b) (4)	12 Apr 2021 16:11:03
User opened query 'Per ETRTR: According to SAE page "Worsening of Left Distal Tibia Fracture", medication was given for SAE, but the same is missing in this folder. Please add Medications dosing details for SAE or reconcile otherwise, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 20:22:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 18:15:03
User entered 'No (N)'	(b) (4), (b) (6)	13 Aug 2020 19:01:40

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:48:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 07:48:28
Data point term sent to Coder	System	07 Oct 2020 18:25:08
User entered 'ibuprofen'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'left distal tibia fracture'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '800'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'as needed (PRN)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '1 Oct 2020'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:25:05

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Please clarify per source this is HCL/Acetaminophen Oxycodone' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:49:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;OXYCODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:47:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:47:01
Data point term sent to Coder	System	15 Apr 2021 14:13:57
Query 'Please clarify per source this is HCL/Acetaminophen Oxycodone' answered with 'DATA UPDATED.' (Site from CRA).	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:13:45
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:13:29
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:13:29
User entered 'HCL ACETAMINOPHEN OXYCODONE' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:13:29
User opened query 'Please clarify per source this is HCL/Acetaminophen Oxycodone' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:45:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;OXYCODONE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 10:15:22

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 10:15:22
Data point term sent to Coder	System	07 Oct 2020 18:29:13
User entered 'acetaminophen hcl structure oxycodone'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Please clarify per source this is for LEFT DISTAL TIBIA FRACTURE' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:49:10
Query 'Please clarify per source this is for LEFT DISTAL TIBIA FRACTURE' answered with 'DATA UPDATED.' (Site from CRA).	Rosaidaliz Carreira (b) (4)	15 Apr 2021 14:13:47
User entered 'LEFT DISTAL TIBIA FRACTURE' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	15 Apr 2021 14:13:29
User opened query 'Please clarify per source this is for LEFT DISTAL TIBIA FRACTURE' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:43:16
User entered 'acetaminophen hcl structure oxycodone'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:08:21
User closed query 'Please clarify per source this is 5/325' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:08:19
Query 'Please clarify per source this is 5/325' answered with 'Data updated.' (Site from CRA).	Rosaidaliz Carreira (b) (4)	15 Apr 2021 15:57:59
DataPoint Un-verified.	(b) (4)	
	Rosaidaliz Carreira (b) (4)	15 Apr 2021 15:57:41
	(b) (4)	
User entered '5/325' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	15 Apr 2021 15:57:41
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
	(b) (4), (b) (6)	
User opened query 'Please clarify per source this is 5/325' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:49:42
User entered '325'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'three times daily (TID)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Oral (ORAL)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '1 Oct 2020'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Matthew Muniz (b) (4)	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:29:10

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:34:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:34:41
Data point term sent to Coder	System	12 Apr 2021 16:14:17
User entered 'Toradol'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Left popliteal deep vein thrombosis'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '30'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:14:04
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:13:30
User entered 'mg (mg)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty; reason for change Data Entry Error	Surisaday Mederos (b) (4)	12 Apr 2021 16:14:04
User entered '30 mg / 1 ml'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'four times daily (QID)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:13:30
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Apr 2021 16:13:30

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:24:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:24:47
Data point term sent to Coder Coding entries removed.	System Surisaday Mederos (b) (4)	14 Apr 2021 18:24:00 14 Apr 2021 18:23:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:02:46
Data point term sent to Coder User entered 'Zofran'	System Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:19:27 12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 18:26:28
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Please clarify per source this is for Nausea, if for Nausea please add AE term in AE log in source.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:50:29
Query 'Please clarify per source this is for Nausea, if for Nausea please add AE term in AE log in source.' answered with 'Updated' (Site from CRA).	Surisaday Mederos (b) (4)	14 Apr 2021 18:23:29
User entered 'Nausea' reason for change: Data Entry Error	(b) (4)	14 Apr 2021 18:23:22
User opened query 'Please clarify per source this is for Nausea, if for Nausea please add AE term in AE log in source.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:48:37
User entered 'Left Popliteal deep vein thrombosis'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '4'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Every 6 hours.'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:19:18
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:19:18

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:16:07
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 14:16:07
Data point term sent to Coder Coding entries removed.	System Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:15:02 15 Apr 2021 14:14:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: AMBIEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 17:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 17:19:41
Data point term sent to Coder	System	12 Apr 2021 16:29:56
Data point term sent to Coder	System	12 Apr 2021 16:24:35
User entered 'Ambien'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:23:48

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'SLEEP' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	15 Apr 2021 14:14:40
User entered 'Cellulitis of Right Leg.' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Apr 2021 16:29:07
User entered 'Insomnia'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '5'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Bedtime as needed'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:23:48
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:23:48

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:23:48

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:23:48

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME HYDROCHLORIDE, PRODUCTSYNONYM: MAXIPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 07:51:48
Data point term sent to Coder	System	12 Apr 2021 16:26:53
User entered 'Maxipime Sodium Chloride'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Cellulitis of Right leg'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Please clarify, per medical record this should be 50ML the 0.9% is for the solution but 50 ML was given to the subject. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:50:56
Query 'Please clarify, per medical record this should be 50ML the 0.9% is for the solution but 50 ML was given to the subject. ' answered with 'Updated to 50 ml.' (Site from CRA).	Surisaday Mederos (b) (4)	14 Apr 2021 18:13:24
User opened query 'Please clarify, per medical record this should be 50ML the 0.9% is for the solution but 50 ML was given to the subject. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 14:58:49
User entered '50'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mL (mL)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 18:12:49
User entered 'Other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty; reason for change Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 18:12:49
User entered '0.9 % 50 ml'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:25:56
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:25:56

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:45:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 14:45:50
Data point term sent to Coder	System	15 Apr 2021 14:16:04
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:15:14
User entered 'ENOXAPARIN SODIUM' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	15 Apr 2021 14:15:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:51:48
Data point term sent to Coder	System	14 Apr 2021 18:02:55
User entered 'ENOXAPARIN' reason for change: Data Entry Error	Surisaday Mederos (b) (4) (b) (4)	14 Apr 2021 18:02:33
Data point term sent to Coder	System	14 Apr 2021 18:01:54
User closed query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	System	14 Apr 2021 18:00:59

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
Query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' answered with 'Enoxaparin sodium' (Site from System).	Surisaday Mederos (b) (4)	14 Apr 2021 18:00:59
User opened query 'DM-Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4)	14 Apr 2021 13:55:45
Data point term sent to Coder	System	12 Apr 2021 16:27:54
User entered 'Lovenox'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Left Popliteal Deep Vein Thrombosis'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User closed query 'Per medical record this is 75mg or 0.75 ML please choose one they are both equal in value. Please update source as well. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:51:07
Query 'Per medical record this is 75mg or 0.75 ML please choose one they are both equal in value. Please update source as well. ' answered with 'Updated.' (Site from CRA).	Surisaday Mederos (b) (4)	14 Apr 2021 18:02:06
User entered '0.75' reason for change: Data Entry Error	(b) (4)	14 Apr 2021 18:01:52
User opened query 'Per medical record this is 75mg or 0.75 ML please choose one they are both equal in value. Please update source as well. ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:02:05
User entered '75'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mL (mL)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 18:01:52
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:27:53
User entered 'Other (OTHER)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:53
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	12 Apr 2021 16:27:35
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty; reason for change Data Entry Error	Surisaday Mederos (b) (4)	14 Apr 2021 18:01:52
User entered '75 mg/0.75 ml'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Every 12 hours'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Subcutaneous (SUBCUTANEOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:27:35
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:27:35

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:49:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 12:49:48
Data point term sent to Coder	System	12 Apr 2021 16:31:57
User entered 'Percocet'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:31:36

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Left popliteal deep vein thrombosis'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:31:36

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '5/325'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'as needed (PRN)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:31:36
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:31:36

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:31:36

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 16:31:36

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 18:26:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 18:26:23
Data point term sent to Coder	System	12 Apr 2021 17:42:03
User entered 'Vancomycin'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 17:41:17

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Sepsis'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '1250'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Every 12 hours'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '17 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:41:17
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User entered empty.	System	12 Apr 2021 17:41:17

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User entered empty.	System	12 Apr 2021 17:41:17

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:00
User entered empty.	System	12 Apr 2021 17:41:17

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:16:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:16:48
Data point term sent to Coder	System	12 Apr 2021 17:44:05
User entered 'Clindamycin'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Sepsis'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '50'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '600 mg / 50 ml'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Every 8 hours'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 17:43:09

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:18:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:18:05
Data point term sent to Coder	System	12 Apr 2021 18:01:43
User entered 'Valium'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 18:00:52

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Left Popliteal Deep Vein Thrombosis'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 18:00:52

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '2.5'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Every 8 hours PRN'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:00:52
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:00:52

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:00:52

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:00:52

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: SODIUM CHLORIDE;VANCOMYCIN HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 08:03:44
Data point term sent to Coder	System	12 Apr 2021 18:02:44
User entered 'Vancocin and sodium chloride 0.9 %'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 18:02:44

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Sepsis'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '300'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 18:02:44

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	12 Apr 2021 18:02:44
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:02:44

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:02:44

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 18:02:44

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
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)	14 Apr 2021 18:00:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 18:00:52
Data point term sent to Coder	System	14 Apr 2021 17:59:52
User entered 'Influenza vaccine'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Flu prevention'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0.5'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'mL (mL)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'once (ONCE)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'Intramuscular (INTRAMUSCULAR)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered empty.	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Dec 2020'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '0'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered '11 Dec 2020'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:52:52
User entered 'No (N)'	Surisaday Mederos (b) (4)	14 Apr 2021 17:59:04
	(b) (4)	

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User entered empty.	System	14 Apr 2021 17:59:04

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User entered empty.	System	14 Apr 2021 17:59:04

US3352070

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:10:24

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:46:03
User entered empty.	System	14 Apr 2021 17:59:04

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:10:24

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	12 Apr 2021 16:48:33
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Mar 2021 16:10:56

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '14 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:49:33
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'MRI left foot with and without contrast.'	Surisaday Mederos (b) (4) (b) (4)	12 Apr 2021 16:49:33

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:49:33
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:49:33
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '13 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:13

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'MRI ankle with and without contrast left'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:13

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:13
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:13
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:58
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'US Doppler lower extremety venous left.'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:58

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:58
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:27
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:50:58
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:30
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:51:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:30
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'RA Chest 1 view'	Surisaday Mederos (b) (4)	12 Apr 2021 16:51:42

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:30
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Diagnostic (DIAGNOSTIC)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:51:42

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:30
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:51:42
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '11 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:13
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'RA Ankle portable left'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:13
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:13

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:13
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '13 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Irrigation and Debridement left ankle'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:54

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:54

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:52:54
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '13 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:53:44
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Removal of harware ankle surgery'	Surisaday Mederos (b) (4)	12 Apr 2021 16:53:44

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:53:44

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:53:44
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:40
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:54:49
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:40
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'CT angiogram of pulmonary arteries with contrast'	Surisaday Mederos (b) (4)	12 Apr 2021 16:54:49

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:40
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:54:49

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:40
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:54:49
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:18
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Covid 19 antigen BD'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:18
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Diagnostic (DIAGNOSTIC)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:18

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:18
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:10:24

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered '10 Mar 2021'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:37
	(b) (4)	

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:10:24

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'ECG'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:37

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:10:24

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered 'Diagnostic (DIAGNOSTIC)'	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:37

US3352070

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:10:24

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:38:45
User entered empty.	Surisaday Mederos (b) (4)	12 Apr 2021 16:55:37
	(b) (4)	

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
User entered '24/Mar/2021 13:19'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'I'	(b) (4), (b) (6)	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
User entered '29/Mar/2021 08:33'	System	29 Mar 2021 15:33:15

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 15:33:15

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
User entered '12/Apr/2021 06:20'	System	12 Apr 2021 13:20:36

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 13:20:36

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
User entered '13/Apr/2021 12:09'	System	13 Apr 2021 16:10:11

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:58:27
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 16:10:11

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '20/Apr/2021 06:24'	System	20 Apr 2021 13:25:10

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:58:27
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 13:25:10

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'USA-US066-2021-MRNA-1273-P301000008'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Yes (Y)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'No (N)'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Howard'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'schwartz'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '7265 SHeridan Street SUite 210'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'Pembroke Pines'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered 'FL'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
DataPoint Un-verified.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	24 Mar 2021 13:18:47
User entered '33024'	System	24 Mar 2021 13:16:22

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:26:27
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 16:09:51
User entered 'US'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	23 Apr 2021 12:59:00
User entered '5'	System	20 Apr 2021 13:25:10
User entered '4'	System	13 Apr 2021 16:10:11
User entered '3'	System	12 Apr 2021 13:20:36
User entered '2'	System	29 Mar 2021 15:33:15
User entered '1'	System	24 Mar 2021 13:19:03

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:10:24

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '23/Apr/2021 08:58'	System	23 Apr 2021 12:59:00

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 12:59:00

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'USA-US066-2021-MRNA-1273-P301000011'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Howard'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'schwartz'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '7265 SHeridan Street SUite 210'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Pembroke Pines'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'FL'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '33024'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'US'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 13:18:21
User entered '1'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'USA-US066-2021-MRNA-1273-P301000011'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Howard'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'schwartz'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '7265 SHeridan Street SUite 210'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Pembroke Pines'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'FL'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '33024'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'US'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 13:18:21
User entered '1'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered '15/Apr/2021 06:22'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'USA-US066-2021-MRNA-1273-P301000011'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Yes (Y)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'No (N)'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Surisaday'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Howard'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Mederos'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'schwartz'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '9299 SW 152 ST'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '7265 SHeridan Street SUite 210'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered 'Miami'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'Pembroke Pines'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered 'FL'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
Un-reviewed for Safety.	System	23 Apr 2021 12:59:00
User entered '33031'	System	23 Apr 2021 12:59:00
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 13:22:04
User entered '33024'	System	15 Apr 2021 13:21:17

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 20:33:38
User entered 'US'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:24

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 13:18:21
User entered '1'	System	15 Apr 2021 13:22:23

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:24

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:23:16
User entered '28/Apr/2021 06:18'	System	28 Apr 2021 13:18:21

US3352070

Folder: SAE USA-US066-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:24

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.	Howard schwartz (b) (4)	28 Apr 2021 21:23:16
User entered 'I'	(b) (4), (b) (6)	28 Apr 2021 13:18:21