

US3772103 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:41:21

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US3772103

Form: Participant Creation

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

[Participant ID](#)

US3772103

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

US3772103

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Date of Birth (MMM yyyy)	(b) (6) 1967
Age	53
Age Units	YEARS
Age (Derived)	53
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) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 00:58:53

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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) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1977
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 1977
Start Year (derived)	1977
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:36
Height (<i>xxx.x</i>)	178 cm
Weight (<i>xxx.x</i>)	115 kg
BMI (<i>xxx.x</i>)	36.29592 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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) 13 Mar 2021 00:58:53

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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) 13 Mar 2021 00:58:53

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 105616

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) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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)	20 AUG 2020
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:36
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:25
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 09:39 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 09:39

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) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 AUG 2020

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

20 AUG 2020 09:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp 20 AUG 2020 10:31

PC Open Date & Time 20 AUG 2020 09:59

PC Close Date & Time 20 AUG 2020 12:29

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 20 AUG 2020 21:57

PC Open Date & Time 20 AUG 2020 13:24

PC Close Date & Time 21 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 15:44

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 00:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

23 AUG 2020 21:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

98.4 °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

24 AUG 2020 12:22

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 23:54

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:29

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

20 AUG 2020 10:32

PC Open Date & Time

20 AUG 2020 09:59

PC Close Date & Time

20 AUG 2020 12:29

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

20 AUG 2020 21:57

PC Open Date & Time

20 AUG 2020 13:24

PC Close Date & Time

21 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

21 AUG 2020 15:43

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

23 AUG 2020 00:36

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

23 AUG 2020 21:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

24 AUG 2020 12:13

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

25 AUG 2020 23:54

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

26 AUG 2020 12:29

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 10:32
PC Open Date & Time	20 AUG 2020 09:59
PC Close Date & Time	20 AUG 2020 12:29

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Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 21:58
PC Open Date & Time	20 AUG 2020 13:24
PC Close Date & Time	21 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

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 ☒

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 15:43
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

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)

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 00:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

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 ☒

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

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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US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 12:13
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 23:55
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 12:30
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3772103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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)	24 SEP 2020
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 08:35
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:15
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 09:38 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 09:38

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

US3772103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

24 SEP 2020 09:15

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	24 SEP 2020 09:20
Nasopharyngeal Swab 2	No		

US3772103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

98.5 °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

24 SEP 2020 10:13

PC Open Date & Time

24 SEP 2020 09:58

PC Close Date & Time

24 SEP 2020 12:28

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	24 SEP 2020 13:32
PC Open Date & Time	24 SEP 2020 13:23
PC Close Date & Time	25 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

98.5 °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

26 SEP 2020 00:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

98.3 °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

26 SEP 2020 15:29

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 23:13

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

98.4 °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

28 SEP 2020 14:49

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

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

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 15:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

24 SEP 2020 10:14

PC Open Date & Time

24 SEP 2020 09:58

PC Close Date & Time

24 SEP 2020 12:28

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

24 SEP 2020 13:32

PC Open Date & Time

24 SEP 2020 13:23

PC Close Date & Time

25 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

26 SEP 2020 00:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

26 SEP 2020 15:29

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

27 SEP 2020 23:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

28 SEP 2020 14:49

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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 ☐

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

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

30 SEP 2020 15:44

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 10:14
PC Open Date & Time	24 SEP 2020 09:58
PC Close Date & Time	24 SEP 2020 12:28

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 13:33
PC Open Date & Time	24 SEP 2020 13:23
PC Close Date & Time	25 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

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 ☒

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 00:59
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

91 of 2085

EAB) (1725)

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:30
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

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 ☒

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 23:14
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

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)

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 14:49
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

Yes ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 15:44
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3772103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 14:20
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

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.

US3772103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 OCT 2020

Collection time (00:00-23:59)

14:31 (24 HR)

Collection date and time (derived)

29 OCT 2020 14:31

US3772103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:42:01

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

29 OCT 2020 14:21:27

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 NOV 2020 09:29:05

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

17 NOV 2020 14:05:27

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 NOV 2020 11:23:17
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 01:00:34

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 09:41:58

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

16 DEC 2020 21:32:04

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

19 DEC 2020 02:02:58

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 JAN 2021 15:26:19
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 11:52:50

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

19 JAN 2021 22:17:55

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	23 JAN 2021 02:35:03
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 10:05:01

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

08 FEB 2021 21:17:17

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

17 FEB 2021 15:09:39

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 22:24:52
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 20:28:01
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

09 MAR 2021 16:01:39

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

15 MAR 2021 14:42:50

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

23 MAR 2021 15:55:57

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

29 MAR 2021 14:01:21

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 11:10:51

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 08:51:27

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

19 APR 2021 14:48:48

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

27 APR 2021 09:45:49

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 19:51:46

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 <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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Patient Cloud Open Date & Time	14 AUG 2021 00:01
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2021 00:01
Patient Cloud Close Date & Time	06 OCT 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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°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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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23 FEB 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

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02 MAR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 MAR 2022 00:01

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09 MAR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 <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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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30 MAR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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06 APR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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13 APR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 <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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐ Yes ☐

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐ Yes ☐

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Patient Cloud Open Date & Time	15 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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="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"/>

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Patient Cloud Open Date & Time	22 OCT 2022 00:01
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Patient Cloud Close Date & Time	26 OCT 2022 23:59
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US3772103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:41:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 20:27:46

US3772103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 00:58:53

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:30:26

Generated On: 10 Jun 2021 09:41:21

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3772103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

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.

US3772103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

09:14 (24 HR)

Collection date and time (derived)

16 MAR 2021 09:14

US3772103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 22:46:00

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 22:46:00

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3772103

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:41:21

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"/>

US3772103

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:41:21

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3772103

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

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

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

Visit date (dd MMM yyyy)	27 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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US3772103

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	27 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	27 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3772103

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3772103

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 13:45
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 14:42
Temperature (xxx.x)	36.9 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)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

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

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3772103

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

Form: Exposure

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 14:11 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 14:11

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

What was the frequency of the study treatment dosing? ONCE

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

US3772103

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

10:53 (24 HR)

Collection date and time (derived)

27 JAN 2021 10:53

US3772103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00 - 23:59)

10:56

Collection Date and Time (derived)

27 JAN 2021 10:56

US3772103

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

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

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

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

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)	01 MAR 2021
Time of assessment (00:00-23:59)	09:50 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 09:50
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	95 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

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)	01 MAR 2021
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	01 MAR 2021 11:20
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3772103

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3772103

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 01 MAR 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 01 MAR 2021 10:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3772103

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:06

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772103

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 03:01:07

Generated On: 10 Jun 2021 09:41:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772103

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 19:30:26

Generated On: 10 Jun 2021 09:41:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 19:30:26

Generated On: 10 Jun 2021 09:41:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:10 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 14:10
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	73 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772103

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 19:30:26

Generated On: 10 Jun 2021 09:41:21

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.

US3772103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 19:30:26

Generated On: 10 Jun 2021 09:41:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 MAR 2021

Collection time (00:00-23:59)

14:15 (24 HR)

Collection date and time (derived)

30 MAR 2021 14:15

US3772103

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

AEID	USA-US107-2021-MRNA-1273-P30 1000001
Adverse event	ACUTE COLITIS OF SIGMOID AND DESCENDING COLON
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)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	03 JAN 2021
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 (1)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

SUBJECT WAS CONTACTED
REGARDING EDIARY
NONCOMPLIANCE AND
REPORTED HAVING BEEN
HOSPITALIZED FROM 31 DEC
2020 TO 03 JAN 2020. SUBJECT
EXPERIENCED INTENSE
ABDOMINAL PAIN AND FRESH
BLOODY STOOL BEFORE
RUSHING TO THE HOSPITAL
WHERE THEY WERE DX WITH
ACUTE COLITIS OF SIGMOID
AND AND DESCENDING
COLON.

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

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

AEID	
Adverse event	DEPRESSION
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)	13 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 01:16:51

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

AEID	
Adverse event	DOG BITE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 13 Mar 2021 01:16:51

Generated On: 10 Jun 2021 09:41:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Mar 2021 03:00:46

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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Name of Medication TESTOSTERONE CREAM

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 4

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

If dose unit is Other, specify PUMPS

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) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
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 (3)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE COLITIS OF SIGMOID
AND DESCENDING COLON.

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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	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)	03 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication ACUTE COLITIS OF SIGMOID
AND DESCENDING COLON.

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	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)		03 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

Name of Medication CEPHALEXIN

Prophylaxis Yes ☐
No ☒

Indication DOG BITE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 07 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Mar 2021 03:00:45

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Name of Medication LISINOPRIL/
HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	30 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Mar 2021 03:00:45

Generated On: 10 Jun 2021 09:41:21

	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)	02 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3772103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Mar 2021 03:00:46

Generated On: 10 Jun 2021 09:41:21

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3772103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:41:21

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

US3772103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:41:21

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 ☐

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 23 Mar 2021 02:48:25

Generated On: 10 Jun 2021 09:41:21

SAEID	USA-US107-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Mar 2021 02:48:25

Generated On: 10 Jun 2021 09:41:21

SAEID	USA-US107-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/JAN/2021 15:23
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

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Mar 2021 02:48:25

Generated On: 10 Jun 2021 09:41:21

SAEID	USA-US107-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/JAN/2021 09:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3772103 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772103

Form: Participant Creation

Generated On: 10 Jun 2021 09:41:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'US3772103'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:30:25

US3772103

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	20 Aug 2020 16:26:11

US3772103

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:30:26

US3772103

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Clinic (Clinic)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:11

US3772103

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'SCRN'	System	20 Aug 2020 16:26:11

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered (b) (6) 1967'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:30:27

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '53'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'YEARS'	System	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '53'	System	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Male (M)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'I'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	Sarah Sandberg (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:41:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:22

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '20 Aug 2020'	(b) (4) Sarah Sandberg (b) (4)	20 Aug 2020 16:26:42
	(b) (4)	

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'Aug 2020'	System	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '2020'	System	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Amendment 2 (2)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:42

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:30:26

US3772103

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:41:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'I'	System	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:41:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:33:32

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:35:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:35:30
Data point term sent to Coder	System	20 Aug 2020 20:34:41
User entered 'Erectile Dysfunction'	Emily Crews (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'un UNK 2008'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'Jan 2008'	System	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '2008'	System	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered empty.	System	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered empty.	System	20 Aug 2020 20:34:04

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:35:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:35:30
Data point term sent to Coder	System	20 Aug 2020 20:34:43
User entered 'Migraines'	Emily Crews (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'un UNK 1977'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'Jan 1977'	System	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '1977'	System	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered empty.	System	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered empty.	System	20 Aug 2020 20:34:19

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User closed query '16Sep2020(b) (6): Please complete this page. Thank you.' (Site from CRA).	Marisol Corrales (b) (4)	23 Nov 2020 22:35:40
Query '16Sep2020(b) (6): Please complete this page. Thank you.' answered with 'updated' (Site from CRA).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 17:07:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Sep 2020 22:48:51
User opened query '16Sep2020(b) (6): Please complete this page. Thank you.' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 22:48:40
	(b) (4), (b) (6)	30 Sep 2020 22:48:15
	(b) (4), (b) (6)	16 Sep 2020 17:26:54

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Marisol Corrales (b) (4)	23 Nov 2020 22:35:40
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '08:36' reason for change: Data Entry Error	(b) (4)	
	Marisol Corrales (b) (4)	23 Nov 2020 22:35:40
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '20 Aug 2020 08:36'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User closed query 'per CDM: please use drop down menu to enter ND for all vitals if they were not taken during this visit, otherwise please clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 10:13:49
Query 'per CDM: please use drop down menu to enter ND for all vitals if they were not taken during this visit, otherwise please clarify' answered with 'Updated' (Site from DM).	Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:35:49
User entered '178' cm reason for change: Data Entry Error	Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:35:40
User opened query 'per CDM: please use drop down menu to enter ND for all vitals if they were not taken during this visit, otherwise please clarify' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 18:18:10
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15
DataPoint set to visible.	System	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '115' kg reason for change: Data Entry Error	(b) (4)	
	Marisol Corrales (b) (4)	23 Nov 2020 22:35:40
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15
DataPoint set to visible.	System	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered '36.29592'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15
DataPoint set to visible.	System	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'kg/m2'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15
DataPoint set to visible.	System	20 Aug 2020 16:26:48

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:35:40
User closed query 'Data is required. Please provide.' (Site from System).	Marisol Corrales (b) (4)	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:35:40
User closed query 'Data is required. Please provide.' (Site from System).	Marisol Corrales (b) (4)	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'bpm'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:35:40
User closed query 'Data is required. Please provide.' (Site from System).	Marisol Corrales (b) (4)	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'breaths/min'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:35:40
User closed query 'Data is required. Please provide.' (Site from System).	Marisol Corrales (b) (4)	(b) (4)
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:40
User entered empty.	System	30 Sep 2020 22:48:15
	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'mmHg'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:35:40
User closed query 'Data is required. Please provide.' (Site from System).	Marisol Corrales (b) (4)	30 Sep 2020 22:48:40
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	30 Sep 2020 22:48:40
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Sep 2020 22:48:15
User entered empty.	(b) (4), (b) (6)	30 Sep 2020 22:48:15

US3772103

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User entered 'mmHg'	System	23 Nov 2020 22:35:40
User entered empty.	System	30 Sep 2020 22:48:15

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57

US3772103

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:29

US3772103

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '20 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:34:29

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	Emily Crews (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	Emily Crews (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	Emily Crews (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	Emily Crews (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:41:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:57
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:35:43

US3772103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	20 Aug 2020 16:27:04

US3772103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	Sarah Sandberg (b) (4)	20 Aug 2020 16:27:04

US3772103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Clinic (Clinic)'	Sarah Sandberg (b) (4)	20 Aug 2020 16:27:04

US3772103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'VISIT1'	System	20 Aug 2020 16:27:04

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:09:39

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:51:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:51:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 16:09:39
User entered '105616' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:09:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 16:09:39

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	Emily Crews (b) (4)	20 Aug 2020 20:37:49

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	Emily Crews (b) (4)	20 Aug 2020 20:37:49

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:37:49

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:37:49

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	Emily Crews (b) (4)	20 Aug 2020 20:37:49

US3772103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:41:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	Marisol Corrales (b) (4)	23 Nov 2020 22:33:59
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:44:19

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '178' cm	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '115' kg	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '178' cm	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '115' kg	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '08:36'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered '20 Aug 2020 08:36'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '36.9' C	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '82'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'bpm'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '16'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'breaths/min'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '146'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'mmHg'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '96'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'mmHg'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '178' cm	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 22:34:20
User entered '115' kg	Marisol Corrales (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:51:54
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 20:40:54
User entered '10:25'	Emily Crews (b) (4)	20 Aug 2020 20:40:54
	(b) (4)	

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered '20 Aug 2020 10:25'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '36.8' C	Emily Crews (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '66'	Emily Crews (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'bpm'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '14'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'breaths/min'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '146'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'mmHg'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '94'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'mmHg'	System	20 Aug 2020 20:40:54

US3772103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:37:58

US3772103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	Emily Crews (b) (4)	20 Aug 2020 20:37:58

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:39'	Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered '20 Aug 2020 09:39'	System	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Right Arm (RIGHT ARM)'	Sarah Sandberg (b) (4)	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'ONCE'	System	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 17:30:10

US3772103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:22

US3772103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:22

US3772103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:15'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:22

US3772103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered '20 Aug 2020 09:15'	System	20 Aug 2020 20:38:22

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:20'	Emily Crews (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered '20 Aug 2020 09:20'	System	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered empty.	System	20 Aug 2020 20:38:50

US3772103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	20 Aug 2020 20:41:04

US3772103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User entered 'I'	System	20 Aug 2020 20:41:04

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:09', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ff39c988-9c72-44e6-91b4-8c62b6f403f7'	System	20 Aug 2020 17:31:37
User entered 'Yes (Y)'	System	20 Aug 2020 17:31:37

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ff39c988-9c72-44e6-91b4-8c62b6f403f7'	System	20 Aug 2020 17:31:37
User entered '98.2'	System	20 Aug 2020 17:31:37

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ff39c988-9c72-44e6-91b4-8c62b6f403f7'	System	20 Aug 2020 17:31:37
User entered 'No (N)'	System	20 Aug 2020 17:31:37

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:30', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ff39c988-9c72-44e6-91b4-8c62b6f403f7'	System	20 Aug 2020 17:31:37
User entered '20 Aug 2020 10:31'	System	20 Aug 2020 17:31:37

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 09:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 12:29'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:56:40', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a282d461-730a-43e4-a27d-60c05ed113ef'	System	21 Aug 2020 04:57:10
User entered 'Yes (Y)'	System	21 Aug 2020 04:57:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:56:56', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a282d461-730a-43e4-a27d-60c05ed113ef' User entered '97.3'	System	21 Aug 2020 04:57:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a282d461-730a-43e4-a27d-60c05ed113ef'	System	21 Aug 2020 04:57:10
User entered 'No (N)'	System	21 Aug 2020 04:57:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:07', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a282d461-730a-43e4-a27d-60c05ed113ef'	System	21 Aug 2020 04:57:10
User entered '20 Aug 2020 21:57'	System	21 Aug 2020 04:57:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 13:24'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 2'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:44:08', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '165cc67f-2428-4ff0-8d1a-0dad1f0d6ee3'	System	21 Aug 2020 22:44:39
User entered 'Yes (Y)'	System	21 Aug 2020 22:44:39

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:44:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '165cc67f-2428-4ff0-8d1a-0dad1f0d6ee3' User entered '97.7'	System	21 Aug 2020 22:44:39
	System	21 Aug 2020 22:44:39

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:44:29', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '165cc67f-2428-4ff0-8d1a-0dad1f0d6ee3'	System	21 Aug 2020 22:44:39
User entered 'No (N)'	System	21 Aug 2020 22:44:39

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:44:34', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '165cc67f-2428-4ff0-8d1a-0dad1f0d6ee3'	System	21 Aug 2020 22:44:39
User entered '21 Aug 2020 15:44'	System	21 Aug 2020 22:44:39

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 3'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:07', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ceeb3b80-972d-4b51-ad38-a0c108128b4c'	System	23 Aug 2020 07:36:30
User entered 'Yes (Y)'	System	23 Aug 2020 07:36:30

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ceeb3b80-972d-4b51-ad38-a0c108128b4c'	System	23 Aug 2020 07:36:30
User entered '98.2'	System	23 Aug 2020 07:36:30

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:21', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ceeb3b80-972d-4b51-ad38-a0c108128b4c'	System	23 Aug 2020 07:36:30
User entered 'No (N)'	System	23 Aug 2020 07:36:30

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ceeb3b80-972d-4b51-ad38-a0c108128b4c'	System	23 Aug 2020 07:36:30
User entered '23 Aug 2020 00:36'	System	23 Aug 2020 07:36:30

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 4'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '08d64169-18f6-4520-9909-afa6c655c873'	System	24 Aug 2020 04:05:47
User entered 'Yes (Y)'	System	24 Aug 2020 04:05:47

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:33', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '08d64169-18f6-4520-9909-afa6c655c873'	System	24 Aug 2020 04:05:47
User entered '98.6'	System	24 Aug 2020 04:05:47

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:38', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '08d64169-18f6-4520-9909-afa6c655c873'	System	24 Aug 2020 04:05:47
User entered 'No (N)'	System	24 Aug 2020 04:05:47

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:43', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '08d64169-18f6-4520-9909-afa6c655c873'	System	24 Aug 2020 04:05:47
User entered '23 Aug 2020 21:05'	System	24 Aug 2020 04:05:47

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 5'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:21:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5a9fa16c-39af-4f7e-a102-3d49ca0872e9'	System	24 Aug 2020 19:22:10
User entered 'Yes (Y)'	System	24 Aug 2020 19:22:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:21:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5a9fa16c-39af-4f7e-a102-3d49ca0872e9'	System	24 Aug 2020 19:22:10
User entered '98.4'	System	24 Aug 2020 19:22:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:22:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5a9fa16c-39af-4f7e-a102-3d49ca0872e9'	System	24 Aug 2020 19:22:10
User entered 'No (N)'	System	24 Aug 2020 19:22:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:22:07', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5a9fa16c-39af-4f7e-a102-3d49ca0872e9'	System	24 Aug 2020 19:22:10
User entered '24 Aug 2020 12:22'	System	24 Aug 2020 19:22:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 6'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'db7a7691-4f2f-43ef-9ddb-b1bcdec28f7d'	System	26 Aug 2020 06:54:41
User entered 'Yes (Y)'	System	26 Aug 2020 06:54:41

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:30', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'db7a7691-4f2f-43ef-9ddb-b1bcdec28f7d'	System	26 Aug 2020 06:54:41
User entered '97.9'	System	26 Aug 2020 06:54:41

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:32', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'db7a7691-4f2f-43ef-9ddb-b1bcdec28f7d'	System	26 Aug 2020 06:54:41
User entered 'No (N)'	System	26 Aug 2020 06:54:41

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:36', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'db7a7691-4f2f-43ef-9ddb-b1bcdec28f7d'	System	26 Aug 2020 06:54:41
User entered '25 Aug 2020 23:54'	System	26 Aug 2020 06:54:41

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 7'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:11', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2eb9a560-029d-4612-9e38-141cfb25de55'	System	26 Aug 2020 19:29:26
User entered 'Yes (Y)'	System	26 Aug 2020 19:29:26

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:15', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2eb9a560-029d-4612-9e38-141cfb25de55'	System	26 Aug 2020 19:29:26
User entered '98.2'	System	26 Aug 2020 19:29:26

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2eb9a560-029d-4612-9e38-141cfb25de55'	System	26 Aug 2020 19:29:26
User entered 'No (N)'	System	26 Aug 2020 19:29:26

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2eb9a560-029d-4612-9e38-141cfb25de55'	System	26 Aug 2020 19:29:26
User entered '26 Aug 2020 12:29'	System	26 Aug 2020 19:29:26

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:45', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ad8ba79f-070b-4572-8a2a-66a097f361ca'	System	20 Aug 2020 17:32:24
User entered 'None (1)'	System	20 Aug 2020 17:32:24

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:48', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ad8ba79f-070b-4572-8a2a-66a097f361ca'	System	20 Aug 2020 17:32:24
User entered 'No (N)'	System	20 Aug 2020 17:32:24

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:31:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ad8ba79f-070b-4572-8a2a-66a097f361ca'	System	20 Aug 2020 17:32:24
User entered 'No (N)'	System	20 Aug 2020 17:32:24

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ad8ba79f-070b-4572-8a2a-66a097f361ca'	System	20 Aug 2020 17:32:24
User entered 'None (1)'	System	20 Aug 2020 17:32:24

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:20', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ad8ba79f-070b-4572-8a2a-66a097f361ca'	System	20 Aug 2020 17:32:24
User entered '20 Aug 2020 10:32'	System	20 Aug 2020 17:32:24

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 09:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 12:29'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:13', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92a32459-640d-4acd-8e0f-675766efbcd5'	System	21 Aug 2020 04:57:48
User entered 'None (1)'	System	21 Aug 2020 04:57:48

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92a32459-640d-4acd-8e0f-675766efbcd5'	System	21 Aug 2020 04:57:48
User entered 'No (N)'	System	21 Aug 2020 04:57:48

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92a32459-640d-4acd-8e0f-675766efbcd5'	System	21 Aug 2020 04:57:48
User entered 'No (N)'	System	21 Aug 2020 04:57:48

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:36', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92a32459-640d-4acd-8e0f-675766efbcd5'	System	21 Aug 2020 04:57:48
User entered 'None (1)'	System	21 Aug 2020 04:57:48

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:42', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92a32459-640d-4acd-8e0f-675766efbcd5'	System	21 Aug 2020 04:57:48
User entered '20 Aug 2020 21:57'	System	21 Aug 2020 04:57:48

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 13:24'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 2'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:42:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '49876b12-511b-4044-bb73-7128e3d10c86'	System	21 Aug 2020 22:43:36
User entered 'None (1)'	System	21 Aug 2020 22:43:36

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '49876b12-511b-4044-bb73-7128e3d10c86'	System	21 Aug 2020 22:43:36
User entered 'No (N)'	System	21 Aug 2020 22:43:36

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '49876b12-511b-4044-bb73-7128e3d10c86'	System	21 Aug 2020 22:43:36
User entered 'No (N)'	System	21 Aug 2020 22:43:36

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:23', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '49876b12-511b-4044-bb73-7128e3d10c86'	System	21 Aug 2020 22:43:36
User entered 'None (1)'	System	21 Aug 2020 22:43:36

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:31', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '49876b12-511b-4044-bb73-7128e3d10c86'	System	21 Aug 2020 22:43:36
User entered '21 Aug 2020 15:43'	System	21 Aug 2020 22:43:36

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 3'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:41', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'cbe74f2a-2a13-4281-b602-94407ced4fb8'	System	23 Aug 2020 07:36:56
User entered 'None (1)'	System	23 Aug 2020 07:36:56

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'cbe74f2a-2a13-4281-b602-94407ced4fb8'	System	23 Aug 2020 07:36:56
User entered 'No (N)'	System	23 Aug 2020 07:36:56

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'cbe74f2a-2a13-4281-b602-94407ced4fb8'	System	23 Aug 2020 07:36:56
User entered 'No (N)'	System	23 Aug 2020 07:36:56

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'cbe74f2a-2a13-4281-b602-94407ced4fb8'	System	23 Aug 2020 07:36:56
User entered 'None (1)'	System	23 Aug 2020 07:36:56

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'cbe74f2a-2a13-4281-b602-94407ced4fb8'	System	23 Aug 2020 07:36:56
User entered '23 Aug 2020 00:36'	System	23 Aug 2020 07:36:56

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 4'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ec6ad1b3-f05c-4e2a-9097-3c24a784a2eb'	System	24 Aug 2020 04:06:25
User entered 'None (1)'	System	24 Aug 2020 04:06:25

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:05:59', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ec6ad1b3-f05c-4e2a-9097-3c24a784a2eb'	System	24 Aug 2020 04:06:25
User entered 'No (N)'	System	24 Aug 2020 04:06:25

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ec6ad1b3-f05c-4e2a-9097-3c24a784a2eb'	System	24 Aug 2020 04:06:25
User entered 'No (N)'	System	24 Aug 2020 04:06:25

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:09', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ec6ad1b3-f05c-4e2a-9097-3c24a784a2eb'	System	24 Aug 2020 04:06:25
User entered 'None (1)'	System	24 Aug 2020 04:06:25

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ec6ad1b3-f05c-4e2a-9097-3c24a784a2eb'	System	24 Aug 2020 04:06:25
User entered '23 Aug 2020 21:06'	System	24 Aug 2020 04:06:25

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 5'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '20723ab9-d21b-47f2-b3a2-43d04236a9b0'	System	24 Aug 2020 19:13:49
User entered 'None (1)'	System	24 Aug 2020 19:13:49

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:29', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '20723ab9-d21b-47f2-b3a2-43d04236a9b0'	System	24 Aug 2020 19:13:49
User entered 'No (N)'	System	24 Aug 2020 19:13:49

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:33', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '20723ab9-d21b-47f2-b3a2-43d04236a9b0'	System	24 Aug 2020 19:13:49
User entered 'No (N)'	System	24 Aug 2020 19:13:49

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:41', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '20723ab9-d21b-47f2-b3a2-43d04236a9b0'	System	24 Aug 2020 19:13:49
User entered 'None (1)'	System	24 Aug 2020 19:13:49

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '20723ab9-d21b-47f2-b3a2-43d04236a9b0'	System	24 Aug 2020 19:13:49
User entered '24 Aug 2020 12:13'	System	24 Aug 2020 19:13:49

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 6'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:39', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '329366f5-aa1c-41dc-a296-26f9a1895b01'	System	26 Aug 2020 06:54:54
User entered 'None (1)'	System	26 Aug 2020 06:54:54

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:42', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '329366f5-aa1c-41dc-a296-26f9a1895b01'	System	26 Aug 2020 06:54:54
User entered 'No (N)'	System	26 Aug 2020 06:54:54

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '329366f5-aa1c-41dc-a296-26f9a1895b01'	System	26 Aug 2020 06:54:54
User entered 'No (N)'	System	26 Aug 2020 06:54:54

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '329366f5-aa1c-41dc-a296-26f9a1895b01'	System	26 Aug 2020 06:54:54
User entered 'None (1)'	System	26 Aug 2020 06:54:54

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '329366f5-aa1c-41dc-a296-26f9a1895b01'	System	26 Aug 2020 06:54:54
User entered '25 Aug 2020 23:54'	System	26 Aug 2020 06:54:54

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 7'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '234922af-5b55-4c9a-94ce-274fc14766ed'	System	26 Aug 2020 19:29:43
User entered 'None (1)'	System	26 Aug 2020 19:29:43

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:29', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '234922af-5b55-4c9a-94ce-274fc14766ed'	System	26 Aug 2020 19:29:43
User entered 'No (N)'	System	26 Aug 2020 19:29:43

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:33', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '234922af-5b55-4c9a-94ce-274fc14766ed'	System	26 Aug 2020 19:29:43
User entered 'No (N)'	System	26 Aug 2020 19:29:43

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:35', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '234922af-5b55-4c9a-94ce-274fc14766ed'	System	26 Aug 2020 19:29:43
User entered 'None (1)'	System	26 Aug 2020 19:29:43

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:38', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '234922af-5b55-4c9a-94ce-274fc14766ed'	System	26 Aug 2020 19:29:43
User entered '26 Aug 2020 12:29'	System	26 Aug 2020 19:29:43

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:31', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:35', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:40', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:42', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'None (0)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered 'No (N)'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T10:32:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0e4fda9f-c12d-4468-894c-f4405dba9fc7'	System	20 Aug 2020 17:33:01
User entered '20 Aug 2020 10:32'	System	20 Aug 2020 17:33:01

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 09:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 12:29'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:57:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:10', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:20', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:36', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'None (0)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:40', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered 'No (N)'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-20T21:58:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'b5acc09f-988f-4e92-8ba1-f25e2e0675bf'	System	21 Aug 2020 04:58:52
User entered '20 Aug 2020 21:58'	System	21 Aug 2020 04:58:52

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '20 Aug 2020 13:24'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 2'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:37', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:39', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:41', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'None (0)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered 'No (N)'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-21T15:43:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e87b8571-480a-425d-ab89-d8bda47646cf'	System	21 Aug 2020 22:44:04
User entered '21 Aug 2020 15:43'	System	21 Aug 2020 22:44:04

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 3'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:36:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:04', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:08', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'None (0)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:11', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered 'No (N)'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T00:37:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '11019943-a459-47c6-8601-f117d66b88fb'	System	23 Aug 2020 07:37:19
User entered '23 Aug 2020 00:37'	System	23 Aug 2020 07:37:19

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 4'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:31', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:34', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:37', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:45', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'None (0)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered 'No (N)'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-23T21:06:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f55cb1d-1b42-4b2e-94f4-760e40ee61e6'	System	24 Aug 2020 04:06:59
User entered '23 Aug 2020 21:06'	System	24 Aug 2020 04:06:59

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 5'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:12:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:12:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:12:59', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:03', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:08', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'None (0)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered 'No (N)'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-24T12:13:19', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '324f603d-8bfb-4de7-b8d8-2365acf9f76e'	System	24 Aug 2020 19:13:37
User entered '24 Aug 2020 12:13'	System	24 Aug 2020 19:13:37

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 6'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:56', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:54:59', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:55:01', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:55:03', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'None (0)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:55:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered 'No (N)'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-25T23:55:08', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c4295b10-43af-4a31-975d-c3c49024b48d'	System	26 Aug 2020 06:55:13
User entered '25 Aug 2020 23:55'	System	26 Aug 2020 06:55:13

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 7'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:48', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:52', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:55', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:29:59', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'None (0)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:30:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered 'No (N)'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-08-26T12:30:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0951ddca-6e7a-4fd5-ad4c-e13d90fb8e98'	System	26 Aug 2020 19:30:09
User entered '26 Aug 2020 12:30'	System	26 Aug 2020 19:30:09

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 17:30:10

US3772103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:02:42

US3772103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:02:42

US3772103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:02:42

US3772103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:02:42

US3772103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 16:03:07

US3772103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User entered 'I'	System	27 Aug 2020 16:03:07

US3772103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3772103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '04 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3772103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3772103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	04 Sep 2020 18:20:27

US3772103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	Emily Crews (b) (4)	04 Sep 2020 18:20:32

US3772103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:13
User entered 'I'	System	04 Sep 2020 18:20:32

US3772103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:24:08

US3772103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '10 Sep 2020' reason for change: Data Entry Error	System	24 Sep 2020 16:24:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Ruba Zanaid (b) (4)	24 Sep 2020 16:24:13
User entered '10 Sep ' (non-conformant).	(b) (4)	
	System	24 Sep 2020 16:24:08
	Ruba Zanaid (b) (4)	24 Sep 2020 16:24:08
	(b) (4)	

US3772103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ruba Zanaid (b) (4)	24 Sep 2020 16:24:08

US3772103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:24:08

US3772103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:24:21

US3772103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:37:19
User entered 'I'	System	24 Sep 2020 16:24:21

US3772103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:41:50

US3772103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:41:50

US3772103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Clinic (Clinic)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:41:50

US3772103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'VISIT2'	System	24 Sep 2020 16:41:50

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '08:35'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '24 Sep 2020 08:35'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '37.1' C	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '86'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'bpm'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'breaths/min'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '148'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '100'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '10:15'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '24 Sep 2020 10:15'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '37.0' C	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '92'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'bpm'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'breaths/min'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '152'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '100'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	24 Sep 2020 18:25:33

US3772103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:34

US3772103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:34

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:38'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '24 Sep 2020 09:38'	System	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Right Arm (RIGHT ARM)'	Ruba Zanaid (b) (4)	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'ONCE'	System	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 16:42:30

US3772103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:13

US3772103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 12:36:29
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' answered with 'Not yet shipped' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	08 Oct 2020 17:37:52
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24SEP2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking details.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:39:30
User entered '24 Sep 2020'	Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:13

US3772103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:15'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:13

US3772103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '24 Sep 2020 09:15'	System	24 Sep 2020 18:23:13

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '24 Sep 2020'	Emily Crews (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '09:20'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered '24 Sep 2020 09:20'	System	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	Emily Crews (b) (4)	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered empty.	System	24 Sep 2020 18:23:24

US3772103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	24 Sep 2020 16:42:38

US3772103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered 'I'	System	24 Sep 2020 16:42:38

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:28', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '83ee54a1-6387-48fc-b742-3d3048e43e4b'	System	24 Sep 2020 17:13:48
User entered 'Yes (Y)'	System	24 Sep 2020 17:13:48

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:35', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '83ee54a1-6387-48fc-b742-3d3048e43e4b'	System	24 Sep 2020 17:13:48
User entered '98.5'	System	24 Sep 2020 17:13:48

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:39', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '83ee54a1-6387-48fc-b742-3d3048e43e4b'	System	24 Sep 2020 17:13:48
User entered 'No (N)'	System	24 Sep 2020 17:13:48

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '83ee54a1-6387-48fc-b742-3d3048e43e4b'	System	24 Sep 2020 17:13:48
User entered '24 Sep 2020 10:13'	System	24 Sep 2020 17:13:48

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:31:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f48193d6-78b1-440d-8969-0be84e56aa4c'	System	24 Sep 2020 20:32:19
User entered 'Yes (Y)'	System	24 Sep 2020 20:32:19

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:31:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f48193d6-78b1-440d-8969-0be84e56aa4c'	System	24 Sep 2020 20:32:19
User entered '98.3'	System	24 Sep 2020 20:32:19

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:04', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f48193d6-78b1-440d-8969-0be84e56aa4c'	System	24 Sep 2020 20:32:19
User entered 'No (N)'	System	24 Sep 2020 20:32:19

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f48193d6-78b1-440d-8969-0be84e56aa4c'	System	24 Sep 2020 20:32:19
User entered '24 Sep 2020 13:32'	System	24 Sep 2020 20:32:19

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 2'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:58:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '831f1674-4e46-43a8-8688-97f7c28541c4'	System	26 Sep 2020 07:59:15
User entered 'Yes (Y)'	System	26 Sep 2020 07:59:15

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:58:59', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '831f1674-4e46-43a8-8688-97f7c28541c4'	System	26 Sep 2020 07:59:15
User entered '98.5'	System	26 Sep 2020 07:59:15

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '831f1674-4e46-43a8-8688-97f7c28541c4'	System	26 Sep 2020 07:59:15
User entered 'No (N)'	System	26 Sep 2020 07:59:15

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:10', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '831f1674-4e46-43a8-8688-97f7c28541c4'	System	26 Sep 2020 07:59:15
User entered '26 Sep 2020 00:59'	System	26 Sep 2020 07:59:15

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 3'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ba01809c-6208-4a5e-b519-0a5bcc5c5b45'	System	26 Sep 2020 22:29:41
User entered 'Yes (Y)'	System	26 Sep 2020 22:29:41

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:32', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ba01809c-6208-4a5e-b519-0a5bcc5c5b45'	System	26 Sep 2020 22:29:41
User entered '98.3'	System	26 Sep 2020 22:29:41

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:34', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ba01809c-6208-4a5e-b519-0a5bcc5c5b45'	System	26 Sep 2020 22:29:41
User entered 'No (N)'	System	26 Sep 2020 22:29:41

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:39', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ba01809c-6208-4a5e-b519-0a5bcc5c5b45'	System	26 Sep 2020 22:29:41
User entered '26 Sep 2020 15:29'	System	26 Sep 2020 22:29:41

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 4'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:13:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd1a187a6-a518-4860-bd90-c5933315c049'	System	28 Sep 2020 06:14:02
User entered 'Yes (Y)'	System	28 Sep 2020 06:14:02

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:13:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd1a187a6-a518-4860-bd90-c5933315c049' User entered '97.3'	System	28 Sep 2020 06:14:02

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:13:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd1a187a6-a518-4860-bd90-c5933315c049'	System	28 Sep 2020 06:14:02
User entered 'No (N)'	System	28 Sep 2020 06:14:02

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:13:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd1a187a6-a518-4860-bd90-c5933315c049'	System	28 Sep 2020 06:14:02
User entered '27 Sep 2020 23:13'	System	28 Sep 2020 06:14:02

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 5'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:15', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '334805af-6657-4760-a890-495e7e00fee6'	System	28 Sep 2020 21:49:31
User entered 'Yes (Y)'	System	28 Sep 2020 21:49:31

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:21', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '334805af-6657-4760-a890-495e7e00fee6'	System	28 Sep 2020 21:49:31
User entered '98.4'	System	28 Sep 2020 21:49:31

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:24', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '334805af-6657-4760-a890-495e7e00fee6'	System	28 Sep 2020 21:49:31
User entered 'No (N)'	System	28 Sep 2020 21:49:31

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:28', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '334805af-6657-4760-a890-495e7e00fee6'	System	28 Sep 2020 21:49:31
User entered '28 Sep 2020 14:49'	System	28 Sep 2020 21:49:31

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 6'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 7'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f590e055-8d4c-418c-9956-8a803493de1c'	System	30 Sep 2020 22:43:54
User entered 'Yes (Y)'	System	30 Sep 2020 22:43:54

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:40', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f590e055-8d4c-418c-9956-8a803493de1c'	System	30 Sep 2020 22:43:54
User entered '98.1'	System	30 Sep 2020 22:43:54

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:43', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f590e055-8d4c-418c-9956-8a803493de1c'	System	30 Sep 2020 22:43:54
User entered 'No (N)'	System	30 Sep 2020 22:43:54

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f590e055-8d4c-418c-9956-8a803493de1c'	System	30 Sep 2020 22:43:54
User entered '30 Sep 2020 15:43'	System	30 Sep 2020 22:43:54

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5b5ce7cc-0f2a-4650-9406-6826ac16a480'	System	24 Sep 2020 17:14:03
User entered 'None (1)'	System	24 Sep 2020 17:14:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5b5ce7cc-0f2a-4650-9406-6826ac16a480'	System	24 Sep 2020 17:14:03
User entered 'No (N)'	System	24 Sep 2020 17:14:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:55', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5b5ce7cc-0f2a-4650-9406-6826ac16a480'	System	24 Sep 2020 17:14:03
User entered 'No (N)'	System	24 Sep 2020 17:14:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:13:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5b5ce7cc-0f2a-4650-9406-6826ac16a480'	System	24 Sep 2020 17:14:03
User entered 'None (1)'	System	24 Sep 2020 17:14:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5b5ce7cc-0f2a-4650-9406-6826ac16a480'	System	24 Sep 2020 17:14:03
User entered '24 Sep 2020 10:14'	System	24 Sep 2020 17:14:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:20', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '967350ed-e3fa-4b52-96a3-bb2a74bf10eb'	System	24 Sep 2020 20:32:40
User entered 'None (1)'	System	24 Sep 2020 20:32:40

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:24', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '967350ed-e3fa-4b52-96a3-bb2a74bf10eb'	System	24 Sep 2020 20:32:40
User entered 'No (N)'	System	24 Sep 2020 20:32:40

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '967350ed-e3fa-4b52-96a3-bb2a74bf10eb'	System	24 Sep 2020 20:32:40
User entered 'No (N)'	System	24 Sep 2020 20:32:40

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:29', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '967350ed-e3fa-4b52-96a3-bb2a74bf10eb'	System	24 Sep 2020 20:32:40
User entered 'None (1)'	System	24 Sep 2020 20:32:40

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:37', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '967350ed-e3fa-4b52-96a3-bb2a74bf10eb'	System	24 Sep 2020 20:32:40
User entered '24 Sep 2020 13:32'	System	24 Sep 2020 20:32:40

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 2'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ee4a7279-9bf9-482f-a5d3-7fce4c885edf'	System	26 Sep 2020 07:59:36
User entered 'None (1)'	System	26 Sep 2020 07:59:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:17', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ee4a7279-9bf9-482f-a5d3-7fce4c885edf'	System	26 Sep 2020 07:59:36
User entered 'No (N)'	System	26 Sep 2020 07:59:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:20', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ee4a7279-9bf9-482f-a5d3-7fce4c885edf'	System	26 Sep 2020 07:59:36
User entered 'No (N)'	System	26 Sep 2020 07:59:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:23', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ee4a7279-9bf9-482f-a5d3-7fce4c885edf'	System	26 Sep 2020 07:59:36
User entered 'None (1)'	System	26 Sep 2020 07:59:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:31', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ee4a7279-9bf9-482f-a5d3-7fce4c885edf'	System	26 Sep 2020 07:59:36
User entered '26 Sep 2020 00:59'	System	26 Sep 2020 07:59:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 3'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd171b8fd-3bd6-4cad-b392-1bb6dbbf0919'	System	26 Sep 2020 22:30:03
User entered 'None (1)'	System	26 Sep 2020 22:30:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd171b8fd-3bd6-4cad-b392-1bb6dbbf0919'	System	26 Sep 2020 22:30:03
User entered 'No (N)'	System	26 Sep 2020 22:30:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:48', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd171b8fd-3bd6-4cad-b392-1bb6dbbf0919'	System	26 Sep 2020 22:30:03
User entered 'No (N)'	System	26 Sep 2020 22:30:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd171b8fd-3bd6-4cad-b392-1bb6dbbf0919'	System	26 Sep 2020 22:30:03
User entered 'None (1)'	System	26 Sep 2020 22:30:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:29:55', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd171b8fd-3bd6-4cad-b392-1bb6dbbf0919'	System	26 Sep 2020 22:30:03
User entered '26 Sep 2020 15:29'	System	26 Sep 2020 22:30:03

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 4'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '04269734-2b49-4bb4-854c-90f5bf84d9dc'	System	28 Sep 2020 06:14:13
User entered 'None (1)'	System	28 Sep 2020 06:14:13

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:04', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '04269734-2b49-4bb4-854c-90f5bf84d9dc'	System	28 Sep 2020 06:14:13
User entered 'No (N)'	System	28 Sep 2020 06:14:13

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '04269734-2b49-4bb4-854c-90f5bf84d9dc'	System	28 Sep 2020 06:14:13
User entered 'No (N)'	System	28 Sep 2020 06:14:13

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:07', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '04269734-2b49-4bb4-854c-90f5bf84d9dc'	System	28 Sep 2020 06:14:13
User entered 'None (1)'	System	28 Sep 2020 06:14:13

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:09', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '04269734-2b49-4bb4-854c-90f5bf84d9dc'	System	28 Sep 2020 06:14:13
User entered '27 Sep 2020 23:14'	System	28 Sep 2020 06:14:13

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 5'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:32', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '65e7e944-74f4-494e-8403-1463c135d91f'	System	28 Sep 2020 21:49:46
User entered 'None (1)'	System	28 Sep 2020 21:49:46

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:34', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '65e7e944-74f4-494e-8403-1463c135d91f'	System	28 Sep 2020 21:49:46
User entered 'No (N)'	System	28 Sep 2020 21:49:46

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:36', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '65e7e944-74f4-494e-8403-1463c135d91f'	System	28 Sep 2020 21:49:46
User entered 'No (N)'	System	28 Sep 2020 21:49:46

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:38', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '65e7e944-74f4-494e-8403-1463c135d91f'	System	28 Sep 2020 21:49:46
User entered 'None (1)'	System	28 Sep 2020 21:49:46

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:41', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '65e7e944-74f4-494e-8403-1463c135d91f' User entered '28 Sep 2020 14:49'	System	28 Sep 2020 21:49:46
	System	28 Sep 2020 21:49:46

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 6'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 7'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '99b82608-e7b7-49cc-8a2b-0cab761be823'	System	30 Sep 2020 22:44:12
User entered 'None (1)'	System	30 Sep 2020 22:44:12

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:43:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '99b82608-e7b7-49cc-8a2b-0cab761be823'	System	30 Sep 2020 22:44:12
User entered 'No (N)'	System	30 Sep 2020 22:44:12

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '99b82608-e7b7-49cc-8a2b-0cab761be823'	System	30 Sep 2020 22:44:12
User entered 'No (N)'	System	30 Sep 2020 22:44:12

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:03', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '99b82608-e7b7-49cc-8a2b-0cab761be823'	System	30 Sep 2020 22:44:12
User entered 'None (1)'	System	30 Sep 2020 22:44:12

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '99b82608-e7b7-49cc-8a2b-0cab761be823'	System	30 Sep 2020 22:44:12
User entered '30 Sep 2020 15:44'	System	30 Sep 2020 22:44:12

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:09', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'None (0)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:23', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered 'No (N)'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T10:14:26', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '8ddbfd96-8431-4e11-b369-6c94ae8ff529'	System	24 Sep 2020 17:14:29
User entered '24 Sep 2020 10:14'	System	24 Sep 2020 17:14:29

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 09:58'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 12:28'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:42', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:44', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:51', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'None (0)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:32:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered 'No (N)'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-24T13:33:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '05bf1c8b-cdc4-461f-9123-e588752bd35b'	System	24 Sep 2020 20:33:06
User entered '24 Sep 2020 13:33'	System	24 Sep 2020 20:33:06

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '24 Sep 2020 13:23'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 2'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:35', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:37', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:40', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:42', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:45', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'None (0)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered 'No (N)'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T00:59:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '3ca2473a-a68d-4c75-97b6-a9a4cba683b0'	System	26 Sep 2020 07:59:57
User entered '26 Sep 2020 00:59'	System	26 Sep 2020 07:59:57

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 3'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:01', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:03', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:06', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:08', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:11', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:13', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'None (0)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered 'No (N)'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-26T15:30:19', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f36d38d0-5d7f-446b-9353-0c11f283e390'	System	26 Sep 2020 22:30:24
User entered '26 Sep 2020 15:30'	System	26 Sep 2020 22:30:24

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 4'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:16', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:18', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:19', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:21', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'None (0)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered 'No (N)'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-27T23:14:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'a172dee0-13ca-45c0-9948-d812593f8e69'	System	28 Sep 2020 06:14:32
User entered '27 Sep 2020 23:14'	System	28 Sep 2020 06:14:32

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 5'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:45', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:52', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'None (0)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered 'No (N)'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-28T14:49:56', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '46b91360-3394-4bf3-be78-3bfe79e9c498'	System	28 Sep 2020 21:50:00
User entered '28 Sep 2020 14:49'	System	28 Sep 2020 21:50:00

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 6'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	24 Sep 2020 16:42:30
User entered 'Day 7'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:13', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:15', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:17', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:19', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:21', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'None (0)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:24', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered 'No (N)'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-09-30T15:44:33', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6f0ce5c0-c070-446a-9cec-efa345773928'	System	30 Sep 2020 22:44:36
User entered '30 Sep 2020 15:44'	System	30 Sep 2020 22:44:36

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:42:30

US3772103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:41:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:42:30

US3772103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Oct 2020 17:49:13

US3772103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '01 Oct 2020'	Emily Crews (b) (4)	01 Oct 2020 17:49:13

US3772103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4)	01 Oct 2020 17:49:13

US3772103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Oct 2020 17:49:13

US3772103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Oct 2020 17:49:17

US3772103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered 'I'	System	01 Oct 2020 17:49:17

US3772103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	08 Oct 2020 23:30:47

US3772103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '8 Oct 2020'	(b) (4) Matthew Pohlmeier (b) (4)	08 Oct 2020 23:30:47

US3772103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeier (b) (4)	08 Oct 2020 23:30:47

US3772103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	08 Oct 2020 23:30:47

US3772103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	08 Oct 2020 23:30:52

US3772103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered 'I'	System	08 Oct 2020 23:30:52

US3772103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Oct 2020 17:07:53

US3772103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '15 Oct 2020'	Ruba Zanaid (b) (4)	15 Oct 2020 17:07:53

US3772103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Contact Made (CONTACT MADE)'	Ruba Zanaid (b) (4)	15 Oct 2020 17:07:53

US3772103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	Ruba Zanaid (b) (4)	15 Oct 2020 17:07:53

US3772103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	15 Oct 2020 17:07:58

US3772103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered 'I'	System	15 Oct 2020 17:07:58

US3772103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:30
User closed query '21Nov2020(b) (6): Please make sure to complete Visit 3 day 57 folder including VS and immunogenicity assessment. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 16:11:10
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 29OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 18:30:05
Query '21Nov2020(b) (6): Please make sure to complete Visit 3 day 57 folder including VS and immunogenicity assessment. Thank you.' answered with 'Updated' (Site from CRA).	Marisol Corrales (b) (4)	23 Nov 2020 22:27:54
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 29OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' answered with 'update' (Site from DM).	Marisol Corrales (b) (4)	23 Nov 2020 22:27:47
User opened query '21Nov2020(b) (6): Please make sure to complete Visit 3 day 57 folder including VS and immunogenicity assessment. Thank you.' (Site from CRA).	(b) (4), (b) (6)	22 Nov 2020 01:39:15
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 29OCT2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 23:51:56
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:57

US3772103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '29 Oct 2020'	(b) (4) Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:57

US3772103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Clinic (Clinic)'	(b) (4) Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:57

US3772103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'VISIT3'	System	29 Oct 2020 21:20:57

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '29 Oct 2020'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '14:20'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '29 Oct 2020 14:20'	System	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '36.6' C	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Oral (Oral)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '87'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'bpm'	System	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '20'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'breaths/min'	System	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User closed query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate or else clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 07:52:01
Query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate or else clarify' answered with 'NCS per PI' (Site from DM).	Emily Crews (b) (4) (b) (4)	29 Dec 2020 23:32:06
User opened query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate or else clarify' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 16:18:39
User entered '158'	Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:35
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 16:03:25
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS for the study' (Site from System).	Marisol Corrales (b) (4)	23 Nov 2020 22:26:57
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Nov 2020 22:26:18
User entered '104'	Marisol Corrales (b) (4)	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'mmHg'	System	23 Nov 2020 22:26:18

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47

US3772103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47

US3772103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:39
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'No (N)'	(b) (4) Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:38

US3772103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:39
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:38

US3772103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:27:23

US3772103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '29 Oct 2020'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:27:23

US3772103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered '14:31'	(b) (4) Marisol Corrales (b) (4) (b) (4)	23 Nov 2020 22:27:23

US3772103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered '29 Oct 2020 14:31'	System	23 Nov 2020 22:27:23

US3772103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:52:49
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:42:01
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	29 Oct 2020 21:20:17

US3772103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:47
User entered 'I'	System	29 Oct 2020 21:20:17

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 64'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:44:39
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 71'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-10-29T14:21:09', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '01a520e9-0ecd-4899-8f1d-e124889f3e8e'	System	29 Oct 2020 21:21:34
User entered 'No (N)'	System	29 Oct 2020 21:21:34

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-10-29T14:21:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '01a520e9-0ecd-4899-8f1d-e124889f3e8e'	System	29 Oct 2020 21:21:34
User entered 'No (N)'	System	29 Oct 2020 21:21:34

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-10-29T14:21:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '01a520e9-0ecd-4899-8f1d-e124889f3e8e'	System	29 Oct 2020 21:21:34
User entered '29 Oct 2020 14:21:27'	System	29 Oct 2020 21:21:34

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 78'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-07T09:29:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '24a6ccec-f053-42fe-b6b2-ad1d36274b4c'	System	07 Nov 2020 17:29:09
User entered 'No (N)'	System	07 Nov 2020 17:29:09

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-07T09:29:02', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '24a6cccec-f053-42fe-b6b2-ad1d36274b4c'	System	07 Nov 2020 17:29:09
User entered 'No (N)'	System	07 Nov 2020 17:29:09

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-07T09:29:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '24a6ccec-f053-42fe-b6b2-ad1d36274b4c'	System	07 Nov 2020 17:29:09
User entered '07 Nov 2020 09:29:05'	System	07 Nov 2020 17:29:09

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered 'Day 92'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-17T14:05:22', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '015fbdad-5730-4631-88d1-feab37a023c8'	System	17 Nov 2020 22:05:33
User entered 'No (N)'	System	17 Nov 2020 22:05:33

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-17T14:05:25', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '015fbdad-5730-4631-88d1-feab37a023c8'	System	17 Nov 2020 22:05:33
User entered 'No (N)'	System	17 Nov 2020 22:05:33

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-17T14:05:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '015fbdad-5730-4631-88d1-feab37a023c8'	System	17 Nov 2020 22:05:33
User entered '17 Nov 2020 14:05:27'	System	17 Nov 2020 22:05:33

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 17:30:10

US3772103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:24:36
Data entry locked.	System	20 Aug 2020 17:30:10
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 17:30:10

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2020-11-21T11:23:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ca7a9dde-c1ae-49b6-a525-88222458438b'	System	21 Nov 2020 19:23:21
User entered 'No (N)'	System	21 Nov 2020 19:23:21

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2020-11-21T11:23:15', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ca7a9dde-c1ae-49b6-a525-88222458438b'	System	21 Nov 2020 19:23:21
User entered 'No (N)'	System	21 Nov 2020 19:23:21

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-21T11:23:17', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ca7a9dde-c1ae-49b6-a525-88222458438b'	System	21 Nov 2020 19:23:21
User entered '21 Nov 2020 11:23:17'	System	21 Nov 2020 19:23:21

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2020-11-28T01:00:24', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '131aa9d9-70df-41fc-93da-06fe4be58b68'	System	28 Nov 2020 09:00:40
User entered 'No (N)'	System	28 Nov 2020 09:00:40

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2020-11-28T01:00:27', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '131aa9d9-70df-41fc-93da-06fe4be58b68'	System	28 Nov 2020 09:00:40
User entered 'No (N)'	System	28 Nov 2020 09:00:40

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-11-28T01:00:34', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '131aa9d9-70df-41fc-93da-06fe4be58b68'	System	28 Nov 2020 09:00:40
User entered '28 Nov 2020 01:00:34'	System	28 Nov 2020 09:00:40

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2020-12-09T09:41:23', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'de0fdcdc-6ca5-4407-a862-0ff8ac8ed3dd'	System	09 Dec 2020 17:42:05
User entered 'No (N)'	System	09 Dec 2020 17:42:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2020-12-09T09:41:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'de0fdcdc-6ca5-4407-a862-0ff8ac8ed3dd'	System	09 Dec 2020 17:42:05
User entered 'No (N)'	System	09 Dec 2020 17:42:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-12-09T09:41:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'de0fdcdc-6ca5-4407-a862-0ff8ac8ed3dd'	System	09 Dec 2020 17:42:05
User entered '09 Dec 2020 09:41:58'	System	09 Dec 2020 17:42:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2020-12-16T21:31:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c847a776-6d18-4461-b009-b7551b3f1165'	System	17 Dec 2020 05:32:12
User entered 'No (N)'	System	17 Dec 2020 05:32:12

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2020-12-16T21:32:01', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c847a776-6d18-4461-b009-b7551b3f1165'	System	17 Dec 2020 05:32:12
User entered 'No (N)'	System	17 Dec 2020 05:32:12

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-12-16T21:32:04', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c847a776-6d18-4461-b009-b7551b3f1165' User entered '16 Dec 2020 21:32:04'	System	17 Dec 2020 05:32:12
	System	17 Dec 2020 05:32:12

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2020-12-19T02:02:52', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92709aa3-f024-4db3-90ac-191a23a40774'	System	19 Dec 2020 10:03:00
User entered 'No (N)'	System	19 Dec 2020 10:03:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2020-12-19T02:02:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92709aa3-f024-4db3-90ac-191a23a40774'	System	19 Dec 2020 10:03:00
User entered 'No (N)'	System	19 Dec 2020 10:03:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2020-12-19T02:02:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '92709aa3-f024-4db3-90ac-191a23a40774'	System	19 Dec 2020 10:03:00
User entered '19 Dec 2020 02:02:58'	System	19 Dec 2020 10:03:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-01-05T15:25:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered 'Yes (Y)'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-01-05T15:25:53', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered 'No (N)'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-05T15:25:57', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered 'No (N)'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-05T15:26:05', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered 'Yes (Y)'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-05T15:26:12', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-05T15:26:19', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '210464aa-5f52-4e1d-8c2d-f06dd296f33b'	System	05 Jan 2021 23:26:34
User entered '05 Jan 2021 15:26:19'	System	05 Jan 2021 23:26:34

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-01-11T11:52:43', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0f8a6ce0-4ad0-46f8-9613-93feeeab1d6b'	System	11 Jan 2021 19:52:56
User entered 'No (N)'	System	11 Jan 2021 19:52:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-01-11T11:52:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0f8a6ce0-4ad0-46f8-9613-93feeeab1d6b'	System	11 Jan 2021 19:52:56
User entered 'No (N)'	System	11 Jan 2021 19:52:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-11T11:52:50', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '0f8a6ce0-4ad0-46f8-9613-93feeeab1d6b'	System	11 Jan 2021 19:52:56
User entered '11 Jan 2021 11:52:50'	System	11 Jan 2021 19:52:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-01-19T22:17:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1c35fb04-ecd9-4d55-8d10-95db9e370c0d'	System	20 Jan 2021 06:18:02
User entered 'No (N)'	System	20 Jan 2021 06:18:02

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-01-19T22:17:49', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1c35fb04-ecd9-4d55-8d10-95db9e370c0d'	System	20 Jan 2021 06:18:02
User entered 'No (N)'	System	20 Jan 2021 06:18:02

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-19T22:17:55', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1c35fb04-ecd9-4d55-8d10-95db9e370c0d' User entered '19 Jan 2021 22:17:55'	System	20 Jan 2021 06:18:02

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-01-23T02:34:43', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ae483654-5e21-47a8-aa99-fa832cbb1e79'	System	23 Jan 2021 10:35:06
User entered 'Yes (Y)'	System	23 Jan 2021 10:35:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-01-23T02:34:47', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ae483654-5e21-47a8-aa99-fa832cbb1e79'	System	23 Jan 2021 10:35:06
User entered 'No (N)'	System	23 Jan 2021 10:35:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-23T02:34:52', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ae483654-5e21-47a8-aa99-fa832cbb1e79'	System	23 Jan 2021 10:35:06
User entered 'No (N)'	System	23 Jan 2021 10:35:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-23T02:34:58', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ae483654-5e21-47a8-aa99-fa832cbb1e79'	System	23 Jan 2021 10:35:06
User entered 'No (N)'	System	23 Jan 2021 10:35:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-01-23T02:35:03', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'ae483654-5e21-47a8-aa99-fa832cbb1e79'	System	23 Jan 2021 10:35:06
User entered '23 Jan 2021 02:35:03'	System	23 Jan 2021 10:35:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-02-03T10:04:38', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '019185f5-4aa7-435a-8eef-d60f43587592'	System	03 Feb 2021 18:06:57
User entered 'No (N)'	System	03 Feb 2021 18:06:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-02-03T10:04:54', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '019185f5-4aa7-435a-8eef-d60f43587592'	System	03 Feb 2021 18:06:57
User entered 'No (N)'	System	03 Feb 2021 18:06:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-02-03T10:05:01', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '019185f5-4aa7-435a-8eef-d60f43587592'	System	03 Feb 2021 18:06:57
User entered '03 Feb 2021 10:05:01'	System	03 Feb 2021 18:06:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-02-08T21:17:10', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6cbda6e0-fad6-4087-bdcc-1ba88d8c7664'	System	09 Feb 2021 05:17:22
User entered 'No (N)'	System	09 Feb 2021 05:17:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-02-08T21:17:14', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6cbda6e0-fad6-4087-bdcc-1ba88d8c7664'	System	09 Feb 2021 05:17:22
User entered 'No (N)'	System	09 Feb 2021 05:17:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-02-08T21:17:17', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '6cbda6e0-fad6-4087-bdcc-1ba8d8c7664'	System	09 Feb 2021 05:17:22
User entered '08 Feb 2021 21:17:17'	System	09 Feb 2021 05:17:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-02-17T15:09:33', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd0efc87e-4638-4b7d-98b0-0cc2dd225016'	System	17 Feb 2021 23:13:22
User entered 'No (N)'	System	17 Feb 2021 23:13:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-02-17T15:09:36', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd0efc87e-4638-4b7d-98b0-0cc2dd225016'	System	17 Feb 2021 23:13:22
User entered 'No (N)'	System	17 Feb 2021 23:13:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-02-17T15:09:39', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'd0efc87e-4638-4b7d-98b0-0cc2dd225016'	System	17 Feb 2021 23:13:22
User entered '17 Feb 2021 15:09:39'	System	17 Feb 2021 23:13:22

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-02-22T22:24:41', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2e34d168-a46d-4a6f-a01c-4ad3e63f7d3e'	System	23 Feb 2021 06:24:57
User entered 'No (N)'	System	23 Feb 2021 06:24:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-02-22T22:24:46', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2e34d168-a46d-4a6f-a01c-4ad3e63f7d3e'	System	23 Feb 2021 06:24:57
User entered 'No (N)'	System	23 Feb 2021 06:24:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-02-22T22:24:52', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '2e34d168-a46d-4a6f-a01c-4ad3e63f7d3e' User entered '22 Feb 2021 22:24:52'	System	23 Feb 2021 06:24:57
	System	23 Feb 2021 06:24:57

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (c2f08e1a57e33774)', Time: '2021-03-01T20:27:55-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c6c36d35-280a-48a0-875e-db0b14dda702'	System	02 Mar 2021 04:28:05
User entered 'No (N)'	System	02 Mar 2021 04:28:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (c2f08e1a57e33774)', Time: '2021-03-01T20:27:58-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c6c36d35-280a-48a0-875e-db0b14dda702'	System	02 Mar 2021 04:28:05
User entered 'No (N)'	System	02 Mar 2021 04:28:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-03-01T20:28:01-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'c6c36d35-280a-48a0-875e-db0b14dda702'	System	02 Mar 2021 04:28:05
User entered '01 Mar 2021 20:28:01'	System	02 Mar 2021 04:28:05

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-03-09T16:01:29-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '94351654-4795-405e-be6c-4f596d0818bf' User entered 'No (N)'	System	10 Mar 2021 00:04:54
	System	10 Mar 2021 00:04:54

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-03-09T16:01:34-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '94351654-4795-405e-be6c-4f596d0818bf'	System	10 Mar 2021 00:04:54
User entered 'No (N)'	System	10 Mar 2021 00:04:54

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-03-09T16:01:39-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '94351654-4795-405e-be6c-4f596d0818bf' User entered '09 Mar 2021 16:01:39'	System	10 Mar 2021 00:04:54
	System	10 Mar 2021 00:04:54

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-03-15T14:42:39-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f4d9b6fb-03e3-47b8-9f53-ab7fee19dd82'	System	15 Mar 2021 21:42:52
User entered 'No (N)'	System	15 Mar 2021 21:42:52

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-03-15T14:42:41-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f4d9b6fb-03e3-47b8-9f53-ab7fee19dd82'	System	15 Mar 2021 21:42:52
User entered 'No (N)'	System	15 Mar 2021 21:42:52

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-03-15T14:42:50-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'f4d9b6fb-03e3-47b8-9f53-ab7fee19dd82'	System	15 Mar 2021 21:42:52
User entered '15 Mar 2021 14:42:50'	System	15 Mar 2021 21:42:52

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-03-23T15:55:52-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '9e2ed8c6-f701-4113-99e1-edc1ca7dc725'	System	23 Mar 2021 22:56:00
User entered 'No (N)'	System	23 Mar 2021 22:56:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-03-23T15:55:54-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '9e2ed8c6-f701-4113-99e1-edc1ca7dc725'	System	23 Mar 2021 22:56:00
User entered 'No (N)'	System	23 Mar 2021 22:56:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-03-23T15:55:57-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '9e2ed8c6-f701-4113-99e1-edc1ca7dc725'	System	23 Mar 2021 22:56:00
User entered '23 Mar 2021 15:55:57'	System	23 Mar 2021 22:56:00

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-03-29T14:01:13-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '23bdfd51-0e25-4cf0-8112-4aa24f028a26'	System	29 Mar 2021 21:01:29
User entered 'No (N)'	System	29 Mar 2021 21:01:29

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-03-29T14:01:14-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '23bdfd51-0e25-4cf0-8112-4aa24f028a26'	System	29 Mar 2021 21:01:29
User entered 'No (N)'	System	29 Mar 2021 21:01:29

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-03-29T14:01:21-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '23bdfd51-0e25-4cf0-8112-4aa24f028a26' User entered '29 Mar 2021 14:01:21'	System	29 Mar 2021 21:01:29
	System	29 Mar 2021 21:01:29

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-04-05T11:10:46-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5caca2e2-9a49-44f0-b586-4d9695e62c20' User entered 'No (N)'	System	05 Apr 2021 18:10:56
	System	05 Apr 2021 18:10:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-04-05T11:10:49-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5caca2e2-9a49-44f0-b586-4d9695e62c20'	System	05 Apr 2021 18:10:56
User entered 'No (N)'	System	05 Apr 2021 18:10:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-04-05T11:10:51-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '5caca2e2-9a49-44f0-b586-4d9695e62c20'	System	05 Apr 2021 18:10:56
User entered '05 Apr 2021 11:10:51'	System	05 Apr 2021 18:10:56

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-04-13T08:51:24-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'bff60c58-b00e-42d5-a0e4-6c3680b6820c'	System	13 Apr 2021 15:51:35
User entered 'No (N)'	System	13 Apr 2021 15:51:35

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-04-13T08:51:25-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'bff60c58-b00e-42d5-a0e4-6c3680b6820c'	System	13 Apr 2021 15:51:35
User entered 'No (N)'	System	13 Apr 2021 15:51:35

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-04-13T08:51:27-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'bff60c58-b00e-42d5-a0e4-6c3680b6820c'	System	13 Apr 2021 15:51:35
User entered '13 Apr 2021 08:51:27'	System	13 Apr 2021 15:51:35

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-04-19T14:48:43-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '098100cf-7a5e-4725-8146-95420156d836'	System	19 Apr 2021 21:48:51
User entered 'No (N)'	System	19 Apr 2021 21:48:51

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-04-19T14:48:45-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '098100cf-7a5e-4725-8146-95420156d836'	System	19 Apr 2021 21:48:51
User entered 'No (N)'	System	19 Apr 2021 21:48:51

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-04-19T14:48:48-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '098100cf-7a5e-4725-8146-95420156d836'	System	19 Apr 2021 21:48:51
User entered '19 Apr 2021 14:48:48'	System	19 Apr 2021 21:48:51

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-04-27T09:45:43-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e35d0d1a-d941-4016-96e1-2dafa80c2cfd' User entered 'No (N)'	System	29 Apr 2021 04:29:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-04-27T09:45:46-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e35d0d1a-d941-4016-96e1-2dafa80c2cfd'	System	29 Apr 2021 04:29:06
User entered 'No (N)'	System	29 Apr 2021 04:29:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-04-27T09:45:49-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: 'e35d0d1a-d941-4016-96e1-2dafe80c2cfd' User entered '27 Apr 2021 09:45:49'	System	29 Apr 2021 04:29:06
	System	29 Apr 2021 04:29:06

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[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 (34c5c0b9a9d52f5f)', Time: '2021-05-03T19:51:42-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1146e0bf-50dc-4724-9f04-58d0dd6f3bc7'	System	04 May 2021 02:54:01
User entered 'No (N)'	System	04 May 2021 02:54:01

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

Have you been exposed to someone with 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 (34c5c0b9a9d52f5f)', Time: '2021-05-03T19:51:44-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1146e0bf-50dc-4724-9f04-58d0dd6f3bc7'	System	04 May 2021 02:54:01
User entered 'No (N)'	System	04 May 2021 02:54:01

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (34c5c0b9a9d52f5f)', Time: '2021-05-03T19:51:46-07:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '1146e0bf-50dc-4724-9f04-58d0dd6f3bc7'	System	04 May 2021 02:54:01
User entered '03 May 2021 19:51:46'	System	04 May 2021 02:54:01

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:44:39

US3772103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:41:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:44:39
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:44:39

US3772103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-03-01T20:27:39-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '045a7c81-a325-4942-8809-f3a6f800a340'	System	02 Mar 2021 04:27:55
User entered 'No (N)'	System	02 Mar 2021 04:27:55

US3772103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:41:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:11:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c2f08e1a57e33774)', Time: '2021-03-01T20:27:46-08:00', User OID: 'PatientReportedOutcome (US3772103)', ODM File OID: '045a7c81-a325-4942-8809-f3a6f800a340'	System	02 Mar 2021 04:27:55
User entered '01 Mar 2021 20:27:46'	System	02 Mar 2021 04:27:55

US3772103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	16 Nov 2020 19:35:54

US3772103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered '16 Nov 2020'	(b) (4) Matthew Pohlmeier (b) (4)	16 Nov 2020 19:35:54

US3772103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeier (b) (4)	16 Nov 2020 19:35:54

US3772103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	16 Nov 2020 19:35:54

US3772103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:58:54
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	16 Nov 2020 19:36:00

US3772103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:26:46
User entered 'I'	System	16 Nov 2020 19:36:00

US3772103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:12:24
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	22 Dec 2020 18:43:57

US3772103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:12:24
User entered '22 Dec 2020'	Emily Crews (b) (4) (b) (4)	22 Dec 2020 18:43:57

US3772103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:12:24
User entered 'Contact Made (CONTACT MADE)'	Emily Crews (b) (4) (b) (4)	22 Dec 2020 18:43:57

US3772103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:12:24
User entered empty.	Emily Crews (b) (4) (b) (4)	22 Dec 2020 18:43:57

US3772103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 06:12:29
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	22 Dec 2020 18:44:01

US3772103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered 'I'	System	22 Dec 2020 18:44:01

US3772103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	19 Jan 2021 18:41:59

US3772103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '19 Jan 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	19 Jan 2021 18:41:59

US3772103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	19 Jan 2021 18:41:59

US3772103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	19 Jan 2021 18:41:59

US3772103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	19 Jan 2021 18:42:03

US3772103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered 'I'	System	19 Jan 2021 18:42:03

US3772103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	18 Feb 2021 22:05:36

US3772103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '18 Feb 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	18 Feb 2021 22:05:36

US3772103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	18 Feb 2021 22:05:36

US3772103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	18 Feb 2021 22:05:36

US3772103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	18 Feb 2021 22:05:40

US3772103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:37:26
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered 'I'	System	18 Feb 2021 22:05:40

US3772103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:25:51

US3772103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '16 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:25:51

US3772103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Clinic (Clinic)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:25:51

US3772103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered 'VISIT4'	System	16 Mar 2021 16:25:51

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
User entered empty.	System	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered empty.	System	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered empty.	System	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

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Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered empty.	System	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:45
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered empty.	System	30 Mar 2021 22:17:06

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:49
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'No (N)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:26:20

US3772103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:24:49
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:26:20

US3772103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:25:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:28:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:25:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '16 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:28:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:25:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '09:14'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:28:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
User entered '16 Mar 2021 09:14'	System	16 Mar 2021 16:28:00

US3772103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 19:25:09
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	16 Mar 2021 16:28:04

US3772103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:44:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:35:00
User entered 'I'	System	16 Mar 2021 16:28:04

US3772103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:46:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:56:02

US3772103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:46:00
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:56:02

US3772103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:46:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Apr 2021 21:56:02

US3772103

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:46:00
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:56:02

US3772103

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:46:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 21:56:07

US3772103

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 21:56:07

US3772103

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:10:35

US3772103

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '27 Jan 2021'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:10:35

US3772103

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[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 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Clinic (Clinic)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	27 Jan 2021 19:10:35

US3772103

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

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 19:10:35

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '27 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[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 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:16:36

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:16:36

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '27 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	28 Jan 2021 23:31:43

US3772103

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

Form: Unblinding

Generated On: 10 Jun 2021 09:41:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	28 Jan 2021 23:31:43

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered empty.	System	28 Jan 2021 23:33:30
DataPoint set to visible.	System	28 Jan 2021 23:31:43

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered empty.	System	28 Jan 2021 23:33:30
DataPoint set to visible.	System	28 Jan 2021 23:31:43

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:48:58
User entered '28 Jan 2021' reason for change: Data Entry Error	System	22 Feb 2021 22:48:58
User opened query 'Data is required. Please provide.' (Site from System).	Emily Crews (b) (4)	22 Feb 2021 22:48:50
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	22 Feb 2021 22:48:50
User entered empty; reason for change Data Entry Error	System	22 Feb 2021 22:48:50
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Emily Crews (b) (4)	28 Jan 2021 23:33:30
User entered '28 Jan 2021'	System	28 Jan 2021 23:33:30
	Emily Crews (b) (4)	
	(b) (4)	

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '13:45'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '28 Jan 2021 13:45'	System	22 Feb 2021 22:48:58
User entered empty.	System	22 Feb 2021 22:48:50
User entered '28 Jan 2021 13:45'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '37.1' C	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '80'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'bpm'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'breaths/min'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '143'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '86'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered missing code ND - Not Done.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:41:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered empty.	System	28 Jan 2021 23:33:30
DataPoint set to visible.	System	28 Jan 2021 23:31:43

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:49:30
User entered '28 Jan 2021' reason for change: Data Entry Error	System	22 Feb 2021 22:49:30
User opened query 'Data is required. Please provide.' (Site from System).	Emily Crews (b) (4)	22 Feb 2021 22:49:30
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	22 Feb 2021 22:49:08
User entered empty; reason for change Data Entry Error	System	22 Feb 2021 22:49:08
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Emily Crews (b) (4)	22 Feb 2021 22:49:08
User entered '28 Jan 2021'	(b) (4)	28 Jan 2021 23:33:30
	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '14:42'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '28 Jan 2021 14:42'	System	22 Feb 2021 22:49:30
User entered empty.	System	22 Feb 2021 22:49:08
User entered '28 Jan 2021 14:42'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '36.9' C	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '91'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'bpm'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '16'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'breaths/min'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '142'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '90'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:30

US3772103

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	28 Jan 2021 23:33:30

US3772103

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:33:45

US3772103

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	22 Feb 2021 22:48:37
User entered '28 Jan 2021' reason for change: Data Entry Error	System	22 Feb 2021 22:48:37
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	Emily Crews (b) (4)	22 Feb 2021 22:48:37
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	22 Feb 2021 22:48:31
User entered empty; reason for change Data Entry Error	System	22 Feb 2021 22:48:31
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Emily Crews (b) (4)	22 Feb 2021 22:48:31
User entered '28 Jan 2021'	(b) (4)	28 Jan 2021 23:33:45
	System	28 Jan 2021 23:33:45

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mRNA-1273'	System	28 Jan 2021 23:34:03
DataPoint set to visible.	System	28 Jan 2021 23:31:43

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:22
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered with 'Decision day and OL-1 completed on different days' (Site from System).	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:24
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	28 Jan 2021 23:34:03
User entered '28 Jan 2021'	Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '14:11'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '28 Jan 2021 14:11'	System	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'ONCE'	System	28 Jan 2021 23:34:03

US3772103

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

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 23:34:03

US3772103

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:10:55

US3772103

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Since the sample is still missing in PPD labs, kindly provide Accession number and shipping details for sample dated 27JAN2021 under OL-D1 Visit in query response to confirm with GCL records.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 11:10:42
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Re-Query: Thank you for the response. Since the sample is still missing in PPD labs, kindly provide Accession number and shipping details for sample dated 27JAN2021 under OL-D1 Visit in query response to confirm with GCL records.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:25:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:25:09
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 27JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with 'All samples were shipped from site 15Feb2021' (Site from DM).	Sarah Sandberg (b) (4) (b) (4)	16 Feb 2021 16:21:05

US3772103

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '10:53'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:10:55

US3772103

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '27 Jan 2021 10:53'	System	27 Jan 2021 19:10:55

US3772103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:11:18

US3772103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '27 Jan 2021'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:11:18

US3772103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '10:56'	(b) (4) Marisol Corrales (b) (4)	27 Jan 2021 19:11:18

US3772103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:41:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '27 Jan 2021 10:56'	System	27 Jan 2021 19:11:18

US3772103

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

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	28 Jan 2021 23:34:30

US3772103

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

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	28 Jan 2021 23:34:30

US3772103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	04 Feb 2021 18:43:04

US3772103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '04 Feb 2021'	(b) (4) Marisol Corrales (b) (4)	04 Feb 2021 18:43:04

US3772103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Marisol Corrales (b) (4)	04 Feb 2021 18:43:04

US3772103

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Marisol Corrales (b) (4)	04 Feb 2021 18:43:04

US3772103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	04 Feb 2021 18:43:08

US3772103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	04 Feb 2021 18:43:08

US3772103

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '1'	System	04 Feb 2021 18:43:08
DataPoint set to visible.	System	04 Feb 2021 18:43:08

US3772103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:25:24

US3772103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:25:24

US3772103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[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 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:25:24

US3772103

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'OLD29'	System	01 Mar 2021 22:25:24

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '09:50'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '01 Mar 2021 09:50'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '37.0' C	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '85'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'bpm'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '17'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'breaths/min'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '173'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '95'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '11:20'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '01 Mar 2021 11:20'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '36.6' C	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '70'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'bpm'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '17'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'breaths/min'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '169'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '93'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mmHg'	System	01 Mar 2021 22:26:27

US3772103

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:37

US3772103

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:26:37

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'mRNA-1273'	System	01 Mar 2021 22:27:34
DataPoint set to visible.	System	04 Feb 2021 18:43:08

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '01 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '10:50'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered '01 Mar 2021 10:50'	System	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'ONCE'	System	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:41:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 22:27:34

US3772103

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Mar 2021 22:27:54

US3772103

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	01 Mar 2021 22:27:54

US3772103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	10 Mar 2021 00:06:30

US3772103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered '09 Mar 2021'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	10 Mar 2021 00:06:30

US3772103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	10 Mar 2021 00:06:30

US3772103

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:41:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	10 Mar 2021 00:06:30

US3772103

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:01:07
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	10 Mar 2021 00:06:38

US3772103

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:41:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:58:20
User entered 'I'	System	10 Mar 2021 00:06:38

US3772103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'Yes (Y)'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:15
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '30 Mar 2021'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:15
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'Clinic (Clinic)'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:15
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:41:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	30 Mar 2021 21:28:15

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'Yes (Y)'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '30 Mar 2021'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '14:10'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:10'	System	30 Mar 2021 21:28:48

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '36.7' C	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'Oral (Oral)'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered empty.	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '73'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Mar 2021 21:28:48

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '17'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Mar 2021 21:28:48

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '154'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 21:28:48

US3772103

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '89'	Marisol Corrales (b) (4)	30 Mar 2021 21:28:48
	(b) (4)	

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:41:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Mar 2021 21:28:48

US3772103

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'No (N)'	Marisol Corrales (b) (4)	30 Mar 2021 21:29:00
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:41:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered empty.	Marisol Corrales (b) (4)	30 Mar 2021 21:29:00
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered 'Yes (Y)'	Marisol Corrales (b) (4)	30 Mar 2021 21:29:21
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '30 Mar 2021'	Marisol Corrales (b) (4)	30 Mar 2021 21:29:21
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:30:26
	(b) (4)	
User entered '14:15'	Marisol Corrales (b) (4)	30 Mar 2021 21:29:21
	(b) (4)	

US3772103

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:41:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 14:15'	System	30 Mar 2021 21:29:21

US3772103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:41:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:33
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	05 Jan 2021 23:38:36

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:21:32
User entered 'USA-US107-2021-mRNA-1273-P301000001'	System	06 Jan 2021 15:21:19
User entered 'New'	(b) (4), (b) (6)	06 Jan 2021 15:21:19

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Jan 2021 11:24:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Jan 2021 11:24:05
Data point term sent to Coder	System	22 Jan 2021 19:39:42
Coding entries removed.	Emily Crews (b) (4)	22 Jan 2021 19:39:13
User entered 'Acute colitis of sigmoid and descending colon' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	22 Jan 2021 19:39:13
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis NOS - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 15:57:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 15:57:41
Data point term sent to Coder	System	05 Jan 2021 23:41:49
User entered 'Colitis of Unknown Etiology'	Emily Crews (b) (4)	05 Jan 2021 23:41:24
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '30 Dec 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	22 Jan 2021 19:39:13
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
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)	25 Jan 2021 14:34:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'UPdated' (Site from Safety).	Emily Crews (b) (4)	22 Jan 2021 19:39:21
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 19:39:13
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)	14 Jan 2021 18:34:22
User entered empty.	Emily Crews (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Grade 4 (Grade 4)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '31 Dec 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User closed query ' PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. 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 'DC summary as been emailed to listed email' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:34:21
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).	Emily Crews (b) (4) (b) (4)	22 Jan 2021 19:14:21
User entered '03 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 18:33:51
	Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
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) System	05 Jan 2021 23:41:41
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		05 Jan 2021 23:41:41
User entered 'No (N)' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:41
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	05 Jan 2021 23:41:24
User entered 'Unknown (UNK)'	Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 14:17:20
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)	14 Jan 2021 18:32:53
User entered 'I'	Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
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)	25 Jan 2021 14:35:03
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Udpated' (Site from Safety).	Emily Crews (b) (4)	22 Jan 2021 19:39:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Emily Crews (b) (4)	22 Jan 2021 19:39:13
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)	14 Jan 2021 18:34:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Emily Crews (b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Jan 2021 23:41:24

US3772103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:03:04
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 'In a review of medical records, there was not any COVID-19 testing performed during this subject's hospitalization. ' (Site from Safety).	Sarah Sandberg (b) (4) (b) (4)	03 Feb 2021 19:46:40
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)	01 Feb 2021 21:00:45
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.' canceled (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 14:17:24
User entered 'SUBJECT WAS CONTACTED REGARDING EDIARY NONCOMPLIANCE AND REPORTED HAVING BEEN HOSPITALIZED FROM 31 DEC 2020 TO 03 JAN 2020. SUBJECT EXPERIENCED INTENSE ABDOMINAL PAIN AND FRESH BLOODY STOOL BEFORE RUSHING TO THE HOSPITAL WHERE THEY WERE DX WITH ACUTE COLITIS OF SIGMOID AND AND DESCENDING COLON.' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	22 Jan 2021 19:39:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Narrative](#)

Audit	User	Time (GMT)
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)	14 Jan 2021 18:33:10
User entered 'Subject was contacted regarding eDiary Emily Crews noncompliance and reported having been hospitalized from 31 Dec 2020 to 03 Jan 2020. Subject experienced intense abdominal pain and fresh bloody stool before rushing to the hospital where they were Dx with Colitis of unknown etiology. Medical records have been requested and SAE will be updated when they are received'	(b) (4)	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User entered '0'	System	05 Jan 2021 23:41:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 19:01:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 19:01:40
Data point term sent to Coder	System	15 Feb 2021 19:01:26
User entered 'Depression'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '13 Nov 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User entered empty.	System	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '30 Dec 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User entered empty.	System	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:41:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'I'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User entered '0'	System	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37
User entered '1'	System	15 Feb 2021 19:01:03

US3772103

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Feb 2021 19:02:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 19:02:40
Data point term sent to Coder	System	15 Feb 2021 19:02:27
User entered 'Hypertension'	Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 19:02:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '23 Aug 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 19:02:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 19:02:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Feb 2021 19:02:20
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	System	15 Feb 2021 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:20
User entered empty.	(b) (4)	
	System	15 Feb 2021 19:02:12
	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '1'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 19:02:12
	(b) (4)	

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Feb 2021 19:02:12

US3772103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:41:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 19:02:12

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 20:01:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Feb 2021 20:01:45
Data point term sent to Coder	System	15 Feb 2021 20:01:00
User entered 'Dog bite'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '01 Sep 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User entered empty.	System	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '01 Sep 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User entered empty.	System	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'None (NONE)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'I'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:16:51
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User entered '0'	System	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41
User entered '1'	System	15 Feb 2021 20:00:16

US3772103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:08:41

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:41:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:33
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:42:17

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 09:36:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:36:12
Data point term sent to Coder	System	20 Aug 2020 20:44:03
User entered 'Testosterone Cream'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Erectile Dysfunction'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '4'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Other (OTHER)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'Pumps'	Emily Crews (b) (4)	20 Aug 2020 20:43:08
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	20 Aug 2020 20:43:08
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Topical (TOPICAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:51:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:43:08
User entered 'un UNK 2008'	Emily Crews (b) (4)	20 Aug 2020 20:43:08
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	20 Aug 2020 20:43:08
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:43:08

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User closed query 'Per ETRTR, Please ensure a new entry is completed with concomitant medication used for SAE ACUTE COLITIS OF SIGMOID AND DESCENDING COLON. Thank you' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:45:28
Query 'Per ETRTR, Please ensure a new entry is completed with concomitant medication used for SAE ACUTE COLITIS OF SIGMOID AND DESCENDING COLON. Thank you' answered with 'conmeds added' (Site from CRA).	Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:33:57
User opened query 'Per ETRTR, Please ensure a new entry is completed with concomitant medication used for SAE ACUTE COLITIS OF SIGMOID AND DESCENDING COLON. Thank you' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 23:10:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:38:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:38:12
Data point term sent to Coder	System	20 Aug 2020 20:45:06
User entered 'Imitrex'	Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Migraine'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '25'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'as needed (PRN)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	20 Aug 2020 20:44:07
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Other (OTHER)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Sublingual'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:51:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:44:07
User entered 'un UNK 1990'	Emily Crews (b) (4)	20 Aug 2020 20:44:07
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:44:07

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Feb 2021 08:05:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 08:05:44
Data point term sent to Coder	System	01 Feb 2021 16:35:21
User entered 'Ciprofloxacin'	Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'ACUTE COLITIS OF SIGMOID AND DESCENDING COLON.'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '500'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'twice daily (BID)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '03 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '07 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User entered '2'	System	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User entered '1'	System	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:41
User entered '804 (804)'	System	01 Feb 2021 16:34:38

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 09:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 09:22:45
Data point term sent to Coder	System	01 Feb 2021 16:40:27
User entered 'Flagyl'	Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'ACUTE COLITIS OF SIGMOID AND DESCENDING COLON.'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '250'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'three times daily (TID)'	(b) (4) Emily Crews (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '03 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '09 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User entered '3'	System	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User entered '1'	System	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:00
User entered '804 (804)'	System	01 Feb 2021 16:40:22

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEPHALOXIN [CEFALOXIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Feb 2021 21:36:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Feb 2021 21:36:51
Data point term sent to Coder	System	15 Feb 2021 20:02:01
User entered 'Cephalexin'	Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Dog bite'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '500'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mg (mg)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'twice daily (BID)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Oral (ORAL)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '01 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '07 Sep 2020'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User entered '2'	System	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User entered '1'	System	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:26
User entered '804 (804)'	System	15 Feb 2021 20:01:15

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 18:28:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 18:28:02
Data point term sent to Coder Coding entries removed.	System	04 Mar 2021 18:27:30
	Emily Crews (b) (4)	04 Mar 2021 18:26:36
User entered 'Lisinopril/ HYDROCHLOROTHIAZIDE' reason for change: Data Entry Error	Emily Crews (b) (4)	04 Mar 2021 18:26:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 20:04:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 20:04:48
Data point term sent to Coder	System	15 Feb 2021 20:04:04
User entered 'Hydrochlorothiazide'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Hypertension'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 16:52:15
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated ' (Site from DM).	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:26:42
User entered '20/12.5' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:26:36
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:09:06
User entered '10'	Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'mg (mg)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'once daily (QD)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Oral (ORAL)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered '23 Aug 2020'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 20:03:19
	(b) (4)	

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Feb 2021 20:03:19

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Feb 2021 20:05:53
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 Feb 2021 20:05:53
Data point term sent to Coder	System	15 Feb 2021 20:05:04
User entered 'Duloxetine'	Sarah Sandberg (b) (4) (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Depression'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '20'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mg (mg)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'once daily (QD)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Oral (ORAL)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '13 Nov 2020'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '30 Dec 2020'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User entered '1'	System	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User entered '1'	System	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:04:53
User entered '804 (804)'	System	15 Feb 2021 20:04:14

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
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)	15 Feb 2021 20:06:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 20:06:50
Data point term sent to Coder	System	15 Feb 2021 20:06:10
User entered 'Influenza Vaccine'	Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Influenza Prophylaxis'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0.5'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'mL (mL)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'once (ONCE)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '02 Jan 2021'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '0'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered '02 Jan 2021'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User entered empty.	System	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User entered empty.	System	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:41:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 06:05:06
User entered empty.	System	15 Feb 2021 20:05:16

US3772103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:41:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 03:00:46
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	15 Feb 2021 18:57:50
	(b) (4)	

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'USA-US107-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Jamshid'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Saleh'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '3652 Eureka Way'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Redding'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '96001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:35:34
User entered 'US'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Jan 2021 14:35:57
User entered '1'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'USA-US107-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Jamshid'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Saleh'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '3652 Eureka Way'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Redding'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '96001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:35:34
User entered 'US'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Jan 2021 14:35:57
User entered '1'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
User entered '06/Jan/2021 15:23'	(b) (4) System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:41:21

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.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:35:34
User entered 'I'	(b) (4), (b) (6)	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'USA-US107-2021-MRNA-1273-P301000001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Yes (Y)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'No (N)'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Jamshid'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Saleh'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '3652 Eureka Way'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered 'Redding'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:23:08
User entered '96001'	System	06 Jan 2021 15:21:19

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:35:34
User entered 'US'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:41:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Jan 2021 14:35:57
User entered '1'	System	06 Jan 2021 15:23:16

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
User entered '25/Jan/2021 09:35'	(b) (4) System	25 Jan 2021 14:35:57

US3772103

Folder: SAE USA-US107-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:41:21

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.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:25
User entered 'I'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:35:57