

US3572181 (Prod: Laguna Clinical Research Associates)

Generated By: KC Joubran

Generated On: 10 Jun 2021 08:18:29

All time stamps listed in this document are displayed in GMT

US3572181

Form: Participant Creation

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

Participant ID

US3572181

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

US3572181

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3572181

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3572181

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Were any significant conditions reported?

Yes ☒

No ☐

US3572181

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3572181

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Condition	C-SECTION
Start date (dd MMM yyyy)	12 SEP 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 SEP 2007
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	SEP 2007
Stop Year (derived)	2007

US3572181

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Condition	C-SECTION
Start date (dd MMM yyyy)	05 JUN 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	05 JUN 2004
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JUN 2004
Stop Year (derived)	2004

US3572181

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	12 SEP 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 SEP 2007
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	SEP 2007
Stop Year (derived)	2007

US3572181

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:17
Height (xxx.x)	60 in
Weight (xxx.x)	142 lb
BMI (xxx.x)	27.79046 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572181

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 SEP 2020

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

US3572181

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Mar 2021 03:37:24

Generated On: 10 Jun 2021 08:18:29

Date of assessment (dd MMM yyyy) 3 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) 12 SEP 2007

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3572181

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Mar 2021 03:37:28

Generated On: 10 Jun 2021 08:18:29

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	

US3572181

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 21 Mar 2021 00:15:38

Generated On: 10 Jun 2021 08:18:29

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

What was the participant's randomization number? 111594

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 ☒

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Height	ND - Not Done
Weight	ND - Not Done

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	14:17 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:17
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	113 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	15:03 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:03
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	104 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	173 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	121 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:15:38

Generated On: 10 Jun 2021 08:18:29

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.

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:15:38

Generated On: 10 Jun 2021 08:18:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 14:32

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

US3572181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:38

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	3 SEP 2020 14:23

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:24	3 SEP 2020 14:24
Nasopharyngeal Swab 2	No		

US3572181

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:38

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:00

PC Open Date & Time

03 SEP 2020 14:52

PC Close Date & Time

03 SEP 2020 17:22

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.7 °F

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

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

PC Time Stamp	03 SEP 2020 18:20
PC Open Date & Time	03 SEP 2020 18:17
PC Close Date & Time	04 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:12

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

07 SEP 2020 12:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 13:46

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

09 SEP 2020 12:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 15:01

PC Open Date & Time

03 SEP 2020 14:52

PC Close Date & Time

03 SEP 2020 17:22

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 18:21

PC Open Date & Time

03 SEP 2020 18:17

PC Close Date & Time

04 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 13:47

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:25

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:02
PC Open Date & Time	03 SEP 2020 14:52
PC Close Date & Time	03 SEP 2020 17:22

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:21
PC Open Date & Time	03 SEP 2020 18:17
PC Close Date & Time	04 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

46 of 2178

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

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 ☒

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:13
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

50 of 2178

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

52 of 2178

EAB) (1725)

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:04
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

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)

54 of 2178

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 13:47
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

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 ☒

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:26
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3572181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 SEP 2020

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

Comments
If Contact Not Made, please provide Comments

SUBJECT REPORTS THAT ALL
SX DOCUMENTED IN E-DIARY
(HEADACHE, MUSCLE/JOINT
ACHES, NAUSEA/VOMITING)
WERE MILD AND HAVE
RESOLVED. NO OTHER
COMPLAINTS.

US3572181

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

NO AES REPORTED. SUBJECT
REPORTS DOING WELL.

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:53
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	101 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	12:46 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 12:46
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 12:16 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 12:16

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

US3572181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

12:02 (24 HR)

Collection date and time (derived)

02 OCT 2020 12:02

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Collection date (dd MMM yyyy)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:52	02 OCT 2020 11:52
Nasopharyngeal Swab 2	No		

US3572181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

02 OCT 2020 13:07

PC Open Date & Time

02 OCT 2020 12:36

PC Close Date & Time

02 OCT 2020 15:06

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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 97.6 °F

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

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

PC Time Stamp	02 OCT 2020 16:56
PC Open Date & Time	02 OCT 2020 16:01
PC Close Date & Time	03 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp 03 OCT 2020 12:01

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

04 OCT 2020 16:13

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

05 OCT 2020 12:04

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 12:12

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:04

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 18:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 13:07

PC Open Date & Time

02 OCT 2020 12:36

PC Close Date & Time

02 OCT 2020 15:06

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

02 OCT 2020 16:57

PC Open Date & Time

02 OCT 2020 16:01

PC Close Date & Time

03 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 12:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 16:14

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 12:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 12:13

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:04

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 18:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 13:08
PC Open Date & Time	02 OCT 2020 12:36
PC Close Date & Time	02 OCT 2020 15:06

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 16:57
PC Open Date & Time	02 OCT 2020 16:01
PC Close Date & Time	03 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

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 ☒

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

94 of 2178

EAB) (1725)

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 16:14
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2178

EAB) (1725)

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 2178

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:13
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

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 ☒

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:05
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

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 ☒

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 18:25
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3572181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments SAFETY UNABLE TO REACH PT

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:28

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 NOV 2020
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	02 NOV 2020 16:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3572181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 NOV 2020

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

US3572181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 NOV 2020

Collection time (00:00-23:59)

16:46 (24 HR)

Collection date and time (derived)

02 NOV 2020 16:46

US3572181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 00:15:39

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 04:28:01
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 14:07:47
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 12:18:50

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have 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	05 DEC 2020 04:33:07
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

14 DEC 2020 18:27:40

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 22:05:41
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

26 DEC 2020 07:48:32

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 08:21:55
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 04:30:40

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 04:31:36
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

23 JAN 2021 10:16:54

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 JAN 2021 04:33:02
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 18:58:21

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 09:58:36
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 FEB 2021 15:37:34

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 21:28:41

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 21:29:33

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 07:13:31

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 06:51:10
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

30 MAR 2021 07:22:44

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

03 APR 2021 07:26:01

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 04:44:30

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 20:34:03

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

25 APR 2021 17:55:58

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAY 2021 07:16:00
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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="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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 <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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3572181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:18:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 21:28:15

US3572181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Mar 2021 04:18:02

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Mar 2021 04:18:02

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

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) _____

US3572181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

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.

US3572181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 MAR 2021
Collection time (00:00-23:59)	09:04 (24 HR)
Collection date and time (derived)	23 MAR 2021 09:04

US3572181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3572181

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:18:29

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"/>

US3572181

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:18:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3572181

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

Form: Visit Date

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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

Visit date (dd MMM yyyy)	1 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	UNBLND_DECIDE
------------	---------------

US3572181

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 04:33:09

Generated On: 10 Jun 2021 08:18:29

Date of updated informed consent (<i>dd MMM yyyy</i>)	1 MAR 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>)	1 MAR 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

US3572181

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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

US3572181

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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)	10 MAR 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 14:00
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	110 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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)	10 MAR 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 15:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	107 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

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

Form: Physical Examination

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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.

US3572181

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

Form: Exposure

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

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) 10 MAR 2021

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

Treatment Date and Time (derived) 10 MAR 2021 14:59

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

US3572181

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 MAR 2021
Collection time (00:00-23:59)	15:33 (24 HR)
Collection date and time (derived)	1 MAR 2021 15:33

US3572181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 MAR 2021
Collection time (00:00 - 23:59)	15:29
Collection Date and Time (derived)	1 MAR 2021 15:29

US3572181

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

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:41

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 03 Apr 2021 04:42:43

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

OLD29 Placebo Flag

1

US3572181

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 05:00:14

Generated On: 10 Jun 2021 08:18:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Apr 2021 05:00:23

Generated On: 10 Jun 2021 08:18:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 APR 2021
Time of assessment (00:00-23:59)	14:42 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 14:42
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Apr 2021 05:00:23

Generated On: 10 Jun 2021 08:18:29

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 APR 2021
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 16:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	99 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3572181

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 05:00:14

Generated On: 10 Jun 2021 08:18:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 APR 2021

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

US3572181

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Apr 2021 05:00:13

Generated On: 10 Jun 2021 08:18:29

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) 8 APR 2021

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

Treatment Date and Time (derived)

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

US3572181

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 05:00:13

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 05:00:23

Generated On: 10 Jun 2021 08:18:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3572181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 05:00:23

Generated On: 10 Jun 2021 08:18:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3572181

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3572181

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

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.

US3572181

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3572181

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

AEID

Adverse event

ACUTE EXACERBATION OF
HYPERTENSION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

03 SEP 2020

Start time (00:00-23:59)

14:17 (24 HR)

AE start date and time (derived)

03 SEP 2020 14:17

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 SEP 2020

End time (00:00-23:59)

15:08 (24 HR)

AE End Date and Time (derived)

03 SEP 2020 15:08

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

347 of 2178

EAB) (1725)

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

AEID	USA-US091-2021-MRNA-1273-P30 1000008
Adverse event	MULTIPLE FIBROIDS
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)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	28 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 2178

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED SCHEDULED HYSTERECTOMY, INITIAL REPORT. PENDING MEDICAL RECORDS
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
PRODUCTION RELEASE (v12.003 EAB) (1725)	
350 of 2178	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

AEID	USA-US091-2021-MRNA-1273-P30 1000008
Adverse event	FEVER POST HYSTERECTOMY
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)	27 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	03 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2178

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

@1130 CALLED THE SUBJECT
TO FU ON HER RECENT
SURGERY OF HYSTERECTOMY
AND AT WHAT HOSPITAL AND
HER DC DATE. SHE INFORMED
ME SHE WAS AT THE LAREDO
MEDICAL CENTER (MED RECS
FAX 956-796-4228) FROM
27JAN2021 - 03FEB2021. SHE
WAS KEPT AT THE HOSPITAL
LONGER BECAUSE SHE
DEVELOPED A FEVER. (AS OF
01/30/2021 SHE HAD A TEMP OF
99.6). SHE IS CURRENTLY HOME
AND DOING WELL.

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

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

AEID

Adverse event

VAGINAL BLEEDING

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

354 of 2178

EAB) (1725)

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 Apr 2021 04:42:39

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

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

Yes ☐

No ☒

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

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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"/>

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY YEAR/SEASONAL

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

359 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

	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)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

363 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 10:09:49

Generated On: 10 Jun 2021 08:18:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 11 Apr 2021 07:09:50

Generated On: 10 Jun 2021 08:18:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 DEC 2020	BIOPSY OF CERVIX	Diagnostic	
27 JAN 2021	HYSTERECTOMY	Adverse Event	

US3572181

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:18:29

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

US3572181

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:18:29

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 ☐

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/FEB/2021 09:13
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

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/FEB/2021 10:31
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

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/FEB/2021 11:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/FEB/2021 09:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/FEB/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

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	02/MAR/2021 11:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/MAR/2021 11:54
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

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Data signed: (b) (4) 03 Apr 2021 04:42:42

Generated On: 10 Jun 2021 08:18:29

SAEID	USA-US091-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MILTON
Investigator's Last Name	HABER
Site Address: Street	2344 LAGUNA DEL MAR, SUITE 201
Site Address: City	LAREDO
Site Address: State	TX
Site Address: Postal Code	78041
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:36
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3572181 (Prod: Laguna Clinical Research Associates)

US3572181

Form: Participant Creation

Generated On: 10 Jun 2021 08:18:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'US3572181'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:40

US3572181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:12:59

US3572181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:41

US3572181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:12:59

US3572181

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'SCRN'	System	03 Sep 2020 19:12:59

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered (b) (6) 1975'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:42

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '44'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'YEARS'	System	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '44'	System	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Female (F)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:18:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:18

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Sep 2020'	System	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2020'	System	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Amendment 3 (3)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:14:43

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:04:41

US3572181

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:18:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'l'	System	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:18:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:52:17

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:53:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:53:50
Data point term sent to Coder	System	03 Sep 2020 19:52:45
User entered 'Hypertension'	Alisha Lutat (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Un UNK 2017'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Jan 2017'	System	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2017'	System	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered empty.	System	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered empty.	System	03 Sep 2020 19:52:44

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:54:52
Data point term sent to Coder	System	03 Sep 2020 19:53:47
User entered 'C-Section'	Alisha Lutat (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '12 Sep 2007'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '12 Sep 2007'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Sep 2007'	System	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2007'	System	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Sep 2007'	System	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2007'	System	03 Sep 2020 19:53:15

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 19:55:41
Data point term sent to Coder	System	03 Sep 2020 19:54:49
User entered 'C-Section'	Alisha Lutat (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '05 Jun 2004'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '05 Jun 2004'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Jun 2004'	System	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2004'	System	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Jun 2004'	System	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2004'	System	03 Sep 2020 19:54:07

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 23:02:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Feb 2021 23:02:06
Data point term sent to Coder	System	23 Feb 2021 23:01:54
Coding entries removed.	(b) (4), (b) (6)	23 Feb 2021 23:01:04
User entered 'BILATERAL TUBAL LIGATION' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 23:01:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 05:53:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Dec 2020 05:53:26
Data point term sent to Coder	System	30 Dec 2020 05:53:08
User entered 'Tubal Ligation'	(b) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '12 Sep 2007'	(b) (4) (u) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User closed query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 02:58:24
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 07:07:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Feb 2021 07:07:20
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:24:50
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:24:26
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 07:24:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '12 Sep 2007' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	10 Feb 2021 07:07:20
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) (u) (4), (b) (6)	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Sep 2007'	System	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2007'	System	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'Sep 2007'	System	10 Feb 2021 07:07:20
User entered empty.	System	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '2007'	System	10 Feb 2021 07:07:20
User entered empty.	System	30 Dec 2020 05:52:31

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '14:17'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '3 Sep 2020 14:17'	System	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '60' in	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20
DataPoint set to visible.	(b) (4) System	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '142' lb	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20
DataPoint set to visible.	(b) (4) System	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered '27.79046'	System	03 Sep 2020 19:55:20
DataPoint set to visible.	System	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'kg/m2'	System	03 Sep 2020 19:55:20
DataPoint set to visible.	System	03 Sep 2020 19:14:59

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'bpm'	System	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'breaths/min'	System	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'mmHg'	System	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User entered 'mmHg'	System	03 Sep 2020 19:55:20

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49

US3572181

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49

US3572181

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:55:52

US3572181

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:55:52

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User closed query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	25 Feb 2021 06:13:00
Query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' answered with 'Updated MH eCRF to bilateral tubal ligation per patient report' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:02:05
User opened query 'Per DM CLR: Is the participant of childbearing potential? = NO: Surgically Sterile, however, the corresponding procedure is recorded as TUBAL LIGATION. Please confirm if this is Bilateral Tubal Ligation and update recorded procedure as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:08:45
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:49:25

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

If No, what is the reason?

Audit	User	Time (GMT)
Query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'updated per source, MH eCRF updated per source. Condition associated with procedure is unknown' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:53:49
User opened query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 11:08:11
User entered 'Surgically sterile (SURGICALLY STERILE)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered '12 Sep 2007' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 05:53:00
User entered '01 Sep 2007'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered '0'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered empty.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:18:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:24
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:02:44

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

[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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

[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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

[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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered 'l'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered '0'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:18:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:22:49
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:37:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:03:32

US3572181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:40

US3572181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:40

US3572181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Clinic (Clinic)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:40

US3572181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'VISIT1'	System	03 Sep 2020 20:04:40

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:24:35

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '111594'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:24:35

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:24:35

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:58

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:04:58

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:58

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:58

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:04:58

US3572181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:10:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:16:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:16:43

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Pre-Dose (PREDOSE)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '14:17'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '3 Sep 2020 14:17'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '97.9' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '104'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'bpm'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'breaths/min'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User closed query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly.' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Jan 2021 06:38:19
Query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly.' answered with 'AE now added' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 00:55:23
User opened query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:10:59
User closed query '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.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 07:09:29
Query '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.' answered with 'AE added ' (Site from System).	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:38:17
User opened query '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.' (Site from System).	System	03 Sep 2020 20:37:08
User entered '171'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User closed query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Jan 2021 06:38:33
Query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' answered with 'AE now added' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 00:56:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' canceled (Site from System).	(b) (4), (b) (6)	18 Sep 2020 07:34:21
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:27:42
User opened query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:13:26
Query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:13:03
User opened query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:11:17
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)	08 Sep 2020 07:11:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

535 of 2178

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
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 'AE added ' (Site from System).	Alisha Lutat (b) (4)	03 Sep 2020 20:38:19
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).		03 Sep 2020 20:37:08
User entered '113'	Alisha Lutat (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered missing code ND - Not Done.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Post-Dose (POSTDOSE)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '15:03'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '3 Sep 2020 15:03'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '97.5' F	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Other (Other)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'temporal'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '104'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'bpm'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '18'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'breaths/min'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User closed query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Jan 2021 06:38:48
Query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' answered with 'AE now added' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 00:56:27
User opened query 'Per CDM: Thank you for the response. For the systolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:11:54
User closed query '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.' (Site from System).	(b) (4), (b) (6)	08 Sep 2020 07:11:45
Query '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.' answered with 'AE added ' (Site from System).	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:38:45
User opened query '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.' (Site from System).	System	03 Sep 2020 20:37:08
User entered '173'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User closed query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	07 Jan 2021 06:39:17
Query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' answered with 'AE now added' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 00:56:33
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' canceled (Site from System).	(b) (4), (b) (6)	18 Sep 2020 07:33:53
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:27:42
User opened query 'Per CDM: Thank you for the response. For the Diastolic BP it was answered as "AE added". However, there was no AE captured for the subject. Kindly update the AE accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:12:22
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)	08 Sep 2020 07:12:00
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 'AE added ' (Site from System).	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:38:47
User opened 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).	System	03 Sep 2020 20:37:08
User entered '121'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:37:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

554 of 2178

US3572181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	03 Sep 2020 20:37:08

US3572181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:06:59

US3572181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:06:59

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '14:32'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '3 Sep 2020 14:32'	System	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'ONCE'	System	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:35:32

US3572181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:07:38

US3572181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:07:38

US3572181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '14:23'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:07:38

US3572181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '3 Sep 2020 14:23'	System	03 Sep 2020 20:07:38

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '3 Sep 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '14:24'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '3 Sep 2020 14:24'	System	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered empty.	System	03 Sep 2020 20:09:37

US3572181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:09:47

US3572181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'I'	System	03 Sep 2020 20:09:47

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:00:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c6bd5497-d396-457f-a11a-d88d5fdaf503'	System	03 Sep 2020 20:00:53
User entered 'Yes (Y)'	System	03 Sep 2020 20:00:53

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:00:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c6bd5497-d396-457f-a11a-d88d5fdaf503'	System	03 Sep 2020 20:00:53
User entered '97.5'	System	03 Sep 2020 20:00:53

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:00:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c6bd5497-d396-457f-a11a-d88d5fdaf503'	System	03 Sep 2020 20:00:53
User entered 'No (N)'	System	03 Sep 2020 20:00:53

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:00:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c6bd5497-d396-457f-a11a-d88d5fdaf503'	System	03 Sep 2020 20:00:53
User entered '03 Sep 2020 15:00'	System	03 Sep 2020 20:00:53

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 17:22'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:19:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cb525c91-fa83-4694-ac3b-fe60ab84435f'	System	03 Sep 2020 23:20:16
User entered 'Yes (Y)'	System	03 Sep 2020 23:20:16

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:19:55', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cb525c91-fa83-4694-ac3b-fe60ab84435f'	System	03 Sep 2020 23:20:16
User entered '96.7'	System	03 Sep 2020 23:20:16

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cb525c91-fa83-4694-ac3b-fe60ab84435f'	System	03 Sep 2020 23:20:16
User entered 'No (N)'	System	03 Sep 2020 23:20:16

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cb525c91-fa83-4694-ac3b-fe60ab84435f'	System	03 Sep 2020 23:20:16
User entered '03 Sep 2020 18:20'	System	03 Sep 2020 23:20:16

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 18:17'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 2'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:08:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f66e28d2-595e-4f0b-916c-a8f5c12f5b07'	System	04 Sep 2020 17:09:06
User entered 'Yes (Y)'	System	04 Sep 2020 17:09:06

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:08:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f66e28d2-595e-4f0b-916c-a8f5c12f5b07'	System	04 Sep 2020 17:09:06
User entered '97.9'	System	04 Sep 2020 17:09:06

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:08:57', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f66e28d2-595e-4f0b-916c-a8f5c12f5b07'	System	04 Sep 2020 17:09:06
User entered 'No (N)'	System	04 Sep 2020 17:09:06

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f66e28d2-595e-4f0b-916c-a8f5c12f5b07'	System	04 Sep 2020 17:09:06
User entered '04 Sep 2020 12:09'	System	04 Sep 2020 17:09:06

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 3'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:08', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5327b5c9-2a13-499b-8897-c75f866c4f07'	System	05 Sep 2020 17:12:31
User entered 'Yes (Y)'	System	05 Sep 2020 17:12:31

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:18', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5327b5c9-2a13-499b-8897-c75f866c4f07'	System	05 Sep 2020 17:12:31
User entered '97.5'	System	05 Sep 2020 17:12:31

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:24', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5327b5c9-2a13-499b-8897-c75f866c4f07'	System	05 Sep 2020 17:12:31
User entered 'No (N)'	System	05 Sep 2020 17:12:31

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5327b5c9-2a13-499b-8897-c75f866c4f07'	System	05 Sep 2020 17:12:31
User entered '05 Sep 2020 12:12'	System	05 Sep 2020 17:12:31

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 4'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '351fbb91-8dd6-4edc-9181-6e03b937325a'	System	06 Sep 2020 17:02:54
User entered 'Yes (Y)'	System	06 Sep 2020 17:02:54

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '351fbb91-8dd6-4edc-9181-6e03b937325a' User entered '97.5'	System	06 Sep 2020 17:02:54
	System	06 Sep 2020 17:02:54

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '351fbb91-8dd6-4edc-9181-6e03b937325a'	System	06 Sep 2020 17:02:54
User entered 'No (N)'	System	06 Sep 2020 17:02:54

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '351fbb91-8dd6-4edc-9181-6e03b937325a'	System	06 Sep 2020 17:02:54
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:54

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 5'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:02:56', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e7a0f774-98a1-41c6-869f-152babdc3630'	System	07 Sep 2020 17:03:13
User entered 'Yes (Y)'	System	07 Sep 2020 17:03:13

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e7a0f774-98a1-41c6-869f-152babdc3630'	System	07 Sep 2020 17:03:13
User entered '97.5'	System	07 Sep 2020 17:03:13

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:03', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e7a0f774-98a1-41c6-869f-152babdc3630'	System	07 Sep 2020 17:03:13
User entered 'No (N)'	System	07 Sep 2020 17:03:13

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e7a0f774-98a1-41c6-869f-152babdc3630'	System	07 Sep 2020 17:03:13
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 17:03:13

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 6'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:45:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5a926448-97cc-413c-ae51-8e894452860d'	System	08 Sep 2020 18:46:27
User entered 'Yes (Y)'	System	08 Sep 2020 18:46:27

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:04', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5a926448-97cc-413c-ae51-8e894452860d' User entered '97.3'	System	08 Sep 2020 18:46:27
	System	08 Sep 2020 18:46:27

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5a926448-97cc-413c-ae51-8e894452860d'	System	08 Sep 2020 18:46:27
User entered 'No (N)'	System	08 Sep 2020 18:46:27

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5a926448-97cc-413c-ae51-8e894452860d'	System	08 Sep 2020 18:46:27
User entered '08 Sep 2020 13:46'	System	08 Sep 2020 18:46:27

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 7'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:24:41', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'de558a81-de51-4b31-8987-6739598ddb89'	System	09 Sep 2020 17:25:18
User entered 'Yes (Y)'	System	09 Sep 2020 17:25:18

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:09', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'de558a81-de51-4b31-8987-6739598ddb89' User entered '98.2'	System	09 Sep 2020 17:25:18
	System	09 Sep 2020 17:25:18

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'de558a81-de51-4b31-8987-6739598ddb89'	System	09 Sep 2020 17:25:18
User entered 'No (N)'	System	09 Sep 2020 17:25:18

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:16', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'de558a81-de51-4b31-8987-6739598ddb89'	System	09 Sep 2020 17:25:18
User entered '09 Sep 2020 12:25'	System	09 Sep 2020 17:25:18

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:03', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '54a7fdfe-390f-4c35-9d8f-827b18bc9d6b'	System	03 Sep 2020 20:01:39
User entered 'None (1)'	System	03 Sep 2020 20:01:39

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:14', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '54a7fdfe-390f-4c35-9d8f-827b18bc9d6b'	System	03 Sep 2020 20:01:39
User entered 'No (N)'	System	03 Sep 2020 20:01:39

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:20', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '54a7fdfe-390f-4c35-9d8f-827b18bc9d6b'	System	03 Sep 2020 20:01:39
User entered 'No (N)'	System	03 Sep 2020 20:01:39

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:29', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '54a7fdfe-390f-4c35-9d8f-827b18bc9d6b'	System	03 Sep 2020 20:01:39
User entered 'None (1)'	System	03 Sep 2020 20:01:39

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:34', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '54a7fdfe-390f-4c35-9d8f-827b18bc9d6b'	System	03 Sep 2020 20:01:39
User entered '03 Sep 2020 15:01'	System	03 Sep 2020 20:01:39

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 17:22'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '034856ee-32e0-44fa-be6c-56cbc914b161'	System	03 Sep 2020 23:21:02
User entered 'None (1)'	System	03 Sep 2020 23:21:02

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:37', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '034856ee-32e0-44fa-be6c-56cbc914b161'	System	03 Sep 2020 23:21:02
User entered 'No (N)'	System	03 Sep 2020 23:21:02

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:43', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '034856ee-32e0-44fa-be6c-56cbc914b161'	System	03 Sep 2020 23:21:02
User entered 'No (N)'	System	03 Sep 2020 23:21:02

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:20:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '034856ee-32e0-44fa-be6c-56cbc914b161'	System	03 Sep 2020 23:21:02
User entered 'None (1)'	System	03 Sep 2020 23:21:02

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '034856ee-32e0-44fa-be6c-56cbc914b161'	System	03 Sep 2020 23:21:02
User entered '03 Sep 2020 18:21'	System	03 Sep 2020 23:21:02

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 18:17'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 2'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '39af2ec7-50ce-48d6-b83a-ad800d844cb8'	System	04 Sep 2020 17:09:38
User entered 'None (1)'	System	04 Sep 2020 17:09:38

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:23', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '39af2ec7-50ce-48d6-b83a-ad800d844cb8'	System	04 Sep 2020 17:09:38
User entered 'No (N)'	System	04 Sep 2020 17:09:38

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '39af2ec7-50ce-48d6-b83a-ad800d844cb8'	System	04 Sep 2020 17:09:38
User entered 'No (N)'	System	04 Sep 2020 17:09:38

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:29', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '39af2ec7-50ce-48d6-b83a-ad800d844cb8'	System	04 Sep 2020 17:09:38
User entered 'None (1)'	System	04 Sep 2020 17:09:38

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '39af2ec7-50ce-48d6-b83a-ad800d844cb8'	System	04 Sep 2020 17:09:38
User entered '04 Sep 2020 12:09'	System	04 Sep 2020 17:09:38

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 3'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:34', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '62482a2b-f47e-433f-b359-cd9d4d8be660'	System	05 Sep 2020 17:13:06
User entered 'None (1)'	System	05 Sep 2020 17:13:06

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '62482a2b-f47e-433f-b359-cd9d4d8be660'	System	05 Sep 2020 17:13:06
User entered 'No (N)'	System	05 Sep 2020 17:13:06

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '62482a2b-f47e-433f-b359-cd9d4d8be660'	System	05 Sep 2020 17:13:06
User entered 'No (N)'	System	05 Sep 2020 17:13:06

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:12:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '62482a2b-f47e-433f-b359-cd9d4d8be660'	System	05 Sep 2020 17:13:06
User entered 'None (1)'	System	05 Sep 2020 17:13:06

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '62482a2b-f47e-433f-b359-cd9d4d8be660'	System	05 Sep 2020 17:13:06
User entered '05 Sep 2020 12:13'	System	05 Sep 2020 17:13:06

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 4'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:31', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4de508ec-6306-45e1-a600-264a00d972c7'	System	06 Sep 2020 17:03:17
User entered 'None (1)'	System	06 Sep 2020 17:03:17

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:34', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4de508ec-6306-45e1-a600-264a00d972c7'	System	06 Sep 2020 17:03:17
User entered 'No (N)'	System	06 Sep 2020 17:03:17

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:41', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4de508ec-6306-45e1-a600-264a00d972c7'	System	06 Sep 2020 17:03:17
User entered 'No (N)'	System	06 Sep 2020 17:03:17

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4de508ec-6306-45e1-a600-264a00d972c7'	System	06 Sep 2020 17:03:17
User entered 'None (1)'	System	06 Sep 2020 17:03:17

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:53', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4de508ec-6306-45e1-a600-264a00d972c7'	System	06 Sep 2020 17:03:17
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:03:17

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 5'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:10', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a19cf5f3-07f7-4259-a2ba-4103c35b831b'	System	07 Sep 2020 17:03:31
User entered 'None (1)'	System	07 Sep 2020 17:03:31

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:15', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a19cf5f3-07f7-4259-a2ba-4103c35b831b'	System	07 Sep 2020 17:03:31
User entered 'No (N)'	System	07 Sep 2020 17:03:31

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:18', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a19cf5f3-07f7-4259-a2ba-4103c35b831b'	System	07 Sep 2020 17:03:31
User entered 'No (N)'	System	07 Sep 2020 17:03:31

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a19cf5f3-07f7-4259-a2ba-4103c35b831b'	System	07 Sep 2020 17:03:31
User entered 'None (1)'	System	07 Sep 2020 17:03:31

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a19cf5f3-07f7-4259-a2ba-4103c35b831b'	System	07 Sep 2020 17:03:31
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 17:03:31

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 6'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:48', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b4238ae1-d682-4259-98b2-51bb3efd0edc'	System	08 Sep 2020 18:47:15
User entered 'None (1)'	System	08 Sep 2020 18:47:15

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b4238ae1-d682-4259-98b2-51bb3efd0edc'	System	08 Sep 2020 18:47:15
User entered 'No (N)'	System	08 Sep 2020 18:47:15

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b4238ae1-d682-4259-98b2-51bb3efd0edc'	System	08 Sep 2020 18:47:15
User entered 'No (N)'	System	08 Sep 2020 18:47:15

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:46:56', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b4238ae1-d682-4259-98b2-51bb3efd0edc'	System	08 Sep 2020 18:47:15
User entered 'None (1)'	System	08 Sep 2020 18:47:15

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b4238ae1-d682-4259-98b2-51bb3efd0edc'	System	08 Sep 2020 18:47:15
User entered '08 Sep 2020 13:47'	System	08 Sep 2020 18:47:15

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 7'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:23', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c2ab30c2-aa38-4a3b-b07b-71fda54d0cf5'	System	09 Sep 2020 17:25:41
User entered 'None (1)'	System	09 Sep 2020 17:25:41

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c2ab30c2-aa38-4a3b-b07b-71fda54d0cf5'	System	09 Sep 2020 17:25:41
User entered 'No (N)'	System	09 Sep 2020 17:25:41

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:30', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c2ab30c2-aa38-4a3b-b07b-71fda54d0cf5'	System	09 Sep 2020 17:25:41
User entered 'No (N)'	System	09 Sep 2020 17:25:41

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c2ab30c2-aa38-4a3b-b07b-71fda54d0cf5'	System	09 Sep 2020 17:25:41
User entered 'None (1)'	System	09 Sep 2020 17:25:41

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:36', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c2ab30c2-aa38-4a3b-b07b-71fda54d0cf5'	System	09 Sep 2020 17:25:41
User entered '09 Sep 2020 12:25'	System	09 Sep 2020 17:25:41

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:42', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:55', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:01:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:02:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'None (0)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:02:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered 'No (N)'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T15:02:10', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cbf367c7-0bf8-48dc-8524-8f64bba4b61d'	System	03 Sep 2020 20:02:15
User entered '03 Sep 2020 15:02'	System	03 Sep 2020 20:02:15

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 14:52'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 17:22'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:23', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'No interference with activity (1)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:29', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'None (0)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:34', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'None (0)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'None (0)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:41', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'None (0)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'None (0)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered 'No (N)'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-03T18:21:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd7aba8c6-44f7-4f36-ad06-181d11cbc31e'	System	03 Sep 2020 23:21:58
User entered '03 Sep 2020 18:21'	System	03 Sep 2020 23:21:58

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Sep 2020 18:17'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 2'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:40', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'None (0)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:42', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'None (0)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'None (0)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:48', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'None (0)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:09:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:10:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'None (0)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:10:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered 'No (N)'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-04T12:10:18', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '761c5a78-c60f-4b90-b2b9-d527719a54ef'	System	04 Sep 2020 17:10:21
User entered '04 Sep 2020 12:10'	System	04 Sep 2020 17:10:21

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 3'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:07', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:20', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:24', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:29', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'None (0)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered 'No (N)'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-05T12:13:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ccb367d3-1a7a-4d6b-a122-6a96ebfba8e1'	System	05 Sep 2020 17:13:51
User entered '05 Sep 2020 12:13'	System	05 Sep 2020 17:13:51

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 4'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:02:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'None (0)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:04', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'None (0)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'No interference with activity (1)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'No interference with activity (1)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:25', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'None (0)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:27', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'None (0)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered 'No (N)'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-06T12:03:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd5c90ba6-4021-4fd7-91c7-94bb4b26eb98'	System	06 Sep 2020 17:03:57
User entered '06 Sep 2020 12:03'	System	06 Sep 2020 17:03:57

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 5'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:31', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:42', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'None (0)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:03:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered 'No (N)'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-07T12:04:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c876d186-e716-46c7-a633-ceb0b7286b0c'	System	07 Sep 2020 17:04:06
User entered '07 Sep 2020 12:04'	System	07 Sep 2020 17:04:06

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 6'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:16', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:25', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:30', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'None (0)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered 'No (N)'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-08T13:47:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '86fedef7-1462-49e1-b6b5-96b50a27aa92'	System	08 Sep 2020 18:47:41
User entered '08 Sep 2020 13:47'	System	08 Sep 2020 18:47:41

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 7'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:41', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:44', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:53', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:56', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'None (0)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:25:59', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered 'No (N)'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-09-09T12:26:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9c717acc-8a60-4994-8aa6-d4377635a2d3'	System	09 Sep 2020 17:26:07
User entered '09 Sep 2020 12:26'	System	09 Sep 2020 17:26:07

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:35:32

US3572181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:12:39

US3572181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '13 Sep 2020'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:12:39

US3572181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:12:39

US3572181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Subject reports that all sx documented in E-diary (headache, muscle/joint aches, nausea/vomiting) were mild and have resolved. No other complaints.'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:12:39

US3572181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:12:42

US3572181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	20 Sep 2020 20:12:42

US3572181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:13:11

US3572181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '20 Sep 2020'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:13:11

US3572181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:13:11

US3572181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'No AEs reported. Subject reports doing well.'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:13:11

US3572181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Sep 2020 20:13:14

US3572181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	20 Sep 2020 20:13:14

US3572181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	28 Sep 2020 20:02:44

US3572181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '24 Sep 2020'	(b) (4) (u) (4), (b) (6)	28 Sep 2020 20:02:44

US3572181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	28 Sep 2020 20:02:44

US3572181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered empty.	(b) (4) (u) (4), (b) (6)	28 Sep 2020 20:02:44

US3572181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	28 Sep 2020 20:02:51

US3572181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	28 Sep 2020 20:02:51

US3572181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:06:06

US3572181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:06:06

US3572181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:06:06

US3572181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'VISIT2'	System	06 Oct 2020 01:06:06

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '11:53'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Oct 2020 11:53'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '101'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'bpm'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '18'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'breaths/min'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '133'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '91'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '12:46'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Oct 2020 12:46'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '97.5' F	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Temporal'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '95'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'bpm'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '18'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'breaths/min'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '134'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '89'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	06 Oct 2020 01:08:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:37

US3572181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:37

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) Alisha Lutat (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '2 Oct 2020'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '12:16'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '2 Oct 2020 12:16'	System	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'ONCE'	System	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 17:46:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:59

US3572181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:59

US3572181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '12:02'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:08:59

US3572181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Oct 2020 12:02'	System	06 Oct 2020 01:08:59

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Oct 2020'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '11:52'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Oct 2020 11:52'	System	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered empty.	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered empty.	System	06 Oct 2020 01:09:18

US3572181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	06 Oct 2020 01:09:26

US3572181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'I'	System	06 Oct 2020 01:09:26

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:25', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '58fb7e67-b914-4de2-a5b4-6a09f0ad220b'	System	02 Oct 2020 18:07:42
User entered 'Yes (Y)'	System	02 Oct 2020 18:07:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:31', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '58fb7e67-b914-4de2-a5b4-6a09f0ad220b'	System	02 Oct 2020 18:07:42
User entered '97.3'	System	02 Oct 2020 18:07:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:36', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '58fb7e67-b914-4de2-a5b4-6a09f0ad220b'	System	02 Oct 2020 18:07:42
User entered 'No (N)'	System	02 Oct 2020 18:07:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:40', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '58fb7e67-b914-4de2-a5b4-6a09f0ad220b'	System	02 Oct 2020 18:07:42
User entered '02 Oct 2020 13:07'	System	02 Oct 2020 18:07:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 15:06'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:55:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cd79f48c-0f58-42c1-a78c-d82f820d6be6'	System	02 Oct 2020 21:56:19
User entered 'Yes (Y)'	System	02 Oct 2020 21:56:19

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cd79f48c-0f58-42c1-a78c-d82f820d6be6'	System	02 Oct 2020 21:56:19
User entered '97.6'	System	02 Oct 2020 21:56:19

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:15', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cd79f48c-0f58-42c1-a78c-d82f820d6be6'	System	02 Oct 2020 21:56:19
User entered 'No (N)'	System	02 Oct 2020 21:56:19

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:18', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cd79f48c-0f58-42c1-a78c-d82f820d6be6'	System	02 Oct 2020 21:56:19
User entered '02 Oct 2020 16:56'	System	02 Oct 2020 21:56:19

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 16:01'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 2'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:01:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '3460a0eb-32f5-4f53-9612-02e77345f408'	System	03 Oct 2020 17:01:57
User entered 'Yes (Y)'	System	03 Oct 2020 17:01:57

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:01:43', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '3460a0eb-32f5-4f53-9612-02e77345f408'	System	03 Oct 2020 17:01:57
User entered '97.3'	System	03 Oct 2020 17:01:57

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:01:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '3460a0eb-32f5-4f53-9612-02e77345f408'	System	03 Oct 2020 17:01:57
User entered 'No (N)'	System	03 Oct 2020 17:01:57

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:01:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '3460a0eb-32f5-4f53-9612-02e77345f408'	System	03 Oct 2020 17:01:57
User entered '03 Oct 2020 12:01'	System	03 Oct 2020 17:01:57

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 3'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '94ce171d-bd84-4014-80b8-9226cd56dc3f'	System	04 Oct 2020 21:13:54
User entered 'Yes (Y)'	System	04 Oct 2020 21:13:54

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '94ce171d-bd84-4014-80b8-9226cd56dc3f' User entered '97.4'	System	04 Oct 2020 21:13:54
	System	04 Oct 2020 21:13:54

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:48', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '94ce171d-bd84-4014-80b8-9226cd56dc3f'	System	04 Oct 2020 21:13:54
User entered 'No (N)'	System	04 Oct 2020 21:13:54

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '94ce171d-bd84-4014-80b8-9226cd56dc3f' User entered '04 Oct 2020 16:13'	System	04 Oct 2020 21:13:54
	System	04 Oct 2020 21:13:54

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 4'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:03:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b594ed3c-fb46-4a88-9ec6-f173ee2f5fc8'	System	05 Oct 2020 17:04:05
User entered 'Yes (Y)'	System	05 Oct 2020 17:04:05

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:03:56', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b594ed3c-fb46-4a88-9ec6-f173ee2f5fc8'	System	05 Oct 2020 17:04:05
User entered '97.3'	System	05 Oct 2020 17:04:05

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:03:59', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b594ed3c-fb46-4a88-9ec6-f173ee2f5fc8'	System	05 Oct 2020 17:04:05
User entered 'No (N)'	System	05 Oct 2020 17:04:05

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:04:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b594ed3c-fb46-4a88-9ec6-f173ee2f5fc8'	System	05 Oct 2020 17:04:05
User entered '05 Oct 2020 12:04'	System	05 Oct 2020 17:04:05

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 5'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7b6ae822-88cb-4daf-8715-02857f9f7697'	System	06 Oct 2020 17:12:43
User entered 'Yes (Y)'	System	06 Oct 2020 17:12:43

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:24', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7b6ae822-88cb-4daf-8715-02857f9f7697'	System	06 Oct 2020 17:12:43
User entered '97.5'	System	06 Oct 2020 17:12:43

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7b6ae822-88cb-4daf-8715-02857f9f7697'	System	06 Oct 2020 17:12:43
User entered 'No (N)'	System	06 Oct 2020 17:12:43

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7b6ae822-88cb-4daf-8715-02857f9f7697'	System	06 Oct 2020 17:12:43
User entered '06 Oct 2020 12:12'	System	06 Oct 2020 17:12:43

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 6'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:10', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8a74ff4c-20ec-42ff-a824-c8b448bf1110'	System	07 Oct 2020 17:04:35
User entered 'Yes (Y)'	System	07 Oct 2020 17:04:35

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8a74ff4c-20ec-42ff-a824-c8b448bf1110'	System	07 Oct 2020 17:04:35
User entered '97.5'	System	07 Oct 2020 17:04:35

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8a74ff4c-20ec-42ff-a824-c8b448bf1110'	System	07 Oct 2020 17:04:35
User entered 'No (N)'	System	07 Oct 2020 17:04:35

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:31', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8a74ff4c-20ec-42ff-a824-c8b448bf1110'	System	07 Oct 2020 17:04:35
User entered '07 Oct 2020 12:04'	System	07 Oct 2020 17:04:35

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 7'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ce013daf-d890-4382-bc0e-7334f3d18bed'	System	08 Oct 2020 23:24:42
User entered 'Yes (Y)'	System	08 Oct 2020 23:24:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:31', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ce013daf-d890-4382-bc0e-7334f3d18bed' User entered '97.3'	System	08 Oct 2020 23:24:42
	System	08 Oct 2020 23:24:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:36', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ce013daf-d890-4382-bc0e-7334f3d18bed'	System	08 Oct 2020 23:24:42
User entered 'No (N)'	System	08 Oct 2020 23:24:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ce013daf-d890-4382-bc0e-7334f3d18bed'	System	08 Oct 2020 23:24:42
User entered '08 Oct 2020 18:24'	System	08 Oct 2020 23:24:42

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:45', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'eac15f7a-9b5f-4bec-93f2-39c2e8c7aabe'	System	02 Oct 2020 18:08:00
User entered 'None (1)'	System	02 Oct 2020 18:08:00

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:49', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'eac15f7a-9b5f-4bec-93f2-39c2e8c7aabe'	System	02 Oct 2020 18:08:00
User entered 'No (N)'	System	02 Oct 2020 18:08:00

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:51', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'eac15f7a-9b5f-4bec-93f2-39c2e8c7aabe'	System	02 Oct 2020 18:08:00
User entered 'No (N)'	System	02 Oct 2020 18:08:00

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'eac15f7a-9b5f-4bec-93f2-39c2e8c7aabe'	System	02 Oct 2020 18:08:00
User entered 'None (1)'	System	02 Oct 2020 18:08:00

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:07:57', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'eac15f7a-9b5f-4bec-93f2-39c2e8c7aabe'	System	02 Oct 2020 18:08:00
User entered '02 Oct 2020 13:07'	System	02 Oct 2020 18:08:00

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 15:06'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b211f46f-97eb-4388-b27b-e8676217f179'	System	02 Oct 2020 21:57:05
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 21:57:05

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:42', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b211f46f-97eb-4388-b27b-e8676217f179'	System	02 Oct 2020 21:57:05
User entered 'No (N)'	System	02 Oct 2020 21:57:05

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:53', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b211f46f-97eb-4388-b27b-e8676217f179'	System	02 Oct 2020 21:57:05
User entered 'No (N)'	System	02 Oct 2020 21:57:05

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:56:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b211f46f-97eb-4388-b27b-e8676217f179'	System	02 Oct 2020 21:57:05
User entered 'None (1)'	System	02 Oct 2020 21:57:05

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b211f46f-97eb-4388-b27b-e8676217f179'	System	02 Oct 2020 21:57:05
User entered '02 Oct 2020 16:57'	System	02 Oct 2020 21:57:05

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '02 Oct 2020 16:01'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 2'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ec7b2b98-8594-4dd4-b7dc-a3813725fb1b'	System	03 Oct 2020 17:02:40
User entered 'None (1)'	System	03 Oct 2020 17:02:40

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:15', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ec7b2b98-8594-4dd4-b7dc-a3813725fb1b'	System	03 Oct 2020 17:02:40
User entered 'No (N)'	System	03 Oct 2020 17:02:40

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ec7b2b98-8594-4dd4-b7dc-a3813725fb1b'	System	03 Oct 2020 17:02:40
User entered 'No (N)'	System	03 Oct 2020 17:02:40

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ec7b2b98-8594-4dd4-b7dc-a3813725fb1b'	System	03 Oct 2020 17:02:40
User entered 'None (1)'	System	03 Oct 2020 17:02:40

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ec7b2b98-8594-4dd4-b7dc-a3813725fb1b'	System	03 Oct 2020 17:02:40
User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:40

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 3'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cc156963-1c57-411a-986f-e03666420eef'	System	04 Oct 2020 21:14:07
User entered 'None (1)'	System	04 Oct 2020 21:14:07

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:13:57', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cc156963-1c57-411a-986f-e03666420eef'	System	04 Oct 2020 21:14:07
User entered 'No (N)'	System	04 Oct 2020 21:14:07

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cc156963-1c57-411a-986f-e03666420eef'	System	04 Oct 2020 21:14:07
User entered 'No (N)'	System	04 Oct 2020 21:14:07

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cc156963-1c57-411a-986f-e03666420eef'	System	04 Oct 2020 21:14:07
User entered 'None (1)'	System	04 Oct 2020 21:14:07

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:05', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'cc156963-1c57-411a-986f-e03666420eef'	System	04 Oct 2020 21:14:07
User entered '04 Oct 2020 16:14'	System	04 Oct 2020 21:14:07

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 4'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:04:07', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2f09b8c5-68bb-43bd-9142-44b171147c66'	System	05 Oct 2020 17:05:16
User entered 'None (1)'	System	05 Oct 2020 17:05:16

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:04:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2f09b8c5-68bb-43bd-9142-44b171147c66'	System	05 Oct 2020 17:05:16
User entered 'No (N)'	System	05 Oct 2020 17:05:16

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:04:14', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2f09b8c5-68bb-43bd-9142-44b171147c66'	System	05 Oct 2020 17:05:16
User entered 'No (N)'	System	05 Oct 2020 17:05:16

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:04:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2f09b8c5-68bb-43bd-9142-44b171147c66'	System	05 Oct 2020 17:05:16
User entered 'None (1)'	System	05 Oct 2020 17:05:16

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2f09b8c5-68bb-43bd-9142-44b171147c66'	System	05 Oct 2020 17:05:16
User entered '05 Oct 2020 12:05'	System	05 Oct 2020 17:05:16

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 5'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:39', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16916111-c083-452f-84a3-11e42946d24b'	System	06 Oct 2020 17:13:09
User entered 'None (1)'	System	06 Oct 2020 17:13:09

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:43', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16916111-c083-452f-84a3-11e42946d24b'	System	06 Oct 2020 17:13:09
User entered 'No (N)'	System	06 Oct 2020 17:13:09

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16916111-c083-452f-84a3-11e42946d24b'	System	06 Oct 2020 17:13:09
User entered 'No (N)'	System	06 Oct 2020 17:13:09

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:12:49', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16916111-c083-452f-84a3-11e42946d24b'	System	06 Oct 2020 17:13:09
User entered 'None (1)'	System	06 Oct 2020 17:13:09

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16916111-c083-452f-84a3-11e42946d24b'	System	06 Oct 2020 17:13:09
User entered '06 Oct 2020 12:13'	System	06 Oct 2020 17:13:09

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 6'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:37', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f7813af1-d8ca-4ecf-a423-55b982d4633a'	System	07 Oct 2020 17:04:53
User entered 'None (1)'	System	07 Oct 2020 17:04:53

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:40', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f7813af1-d8ca-4ecf-a423-55b982d4633a'	System	07 Oct 2020 17:04:53
User entered 'No (N)'	System	07 Oct 2020 17:04:53

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:44', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f7813af1-d8ca-4ecf-a423-55b982d4633a'	System	07 Oct 2020 17:04:53
User entered 'No (N)'	System	07 Oct 2020 17:04:53

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f7813af1-d8ca-4ecf-a423-55b982d4633a'	System	07 Oct 2020 17:04:53
User entered 'None (1)'	System	07 Oct 2020 17:04:53

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:49', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'f7813af1-d8ca-4ecf-a423-55b982d4633a'	System	07 Oct 2020 17:04:53
User entered '07 Oct 2020 12:04'	System	07 Oct 2020 17:04:53

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 7'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:42', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c693ba46-94a6-4b5e-ab90-c6257a32005e'	System	08 Oct 2020 23:24:58
User entered 'None (1)'	System	08 Oct 2020 23:24:58

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c693ba46-94a6-4b5e-ab90-c6257a32005e'	System	08 Oct 2020 23:24:58
User entered 'No (N)'	System	08 Oct 2020 23:24:58

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c693ba46-94a6-4b5e-ab90-c6257a32005e'	System	08 Oct 2020 23:24:58
User entered 'No (N)'	System	08 Oct 2020 23:24:58

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c693ba46-94a6-4b5e-ab90-c6257a32005e'	System	08 Oct 2020 23:24:58
User entered 'None (1)'	System	08 Oct 2020 23:24:58

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c693ba46-94a6-4b5e-ab90-c6257a32005e'	System	08 Oct 2020 23:24:58
User entered '08 Oct 2020 18:24'	System	08 Oct 2020 23:24:58

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:04', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:07', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:10', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:16', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'None (0)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered 'No (N)'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T13:08:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0844fd7-2068-4636-b744-d70e17e24010'	System	02 Oct 2020 18:08:23
User entered '02 Oct 2020 13:08'	System	02 Oct 2020 18:08:23

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '02 Oct 2020 12:36'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '02 Oct 2020 15:06'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:09', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'None (0)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:27', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered 'No (N)'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-02T16:57:30', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8896d9-eedb-499e-85af-9a8ab47576c3'	System	02 Oct 2020 21:57:33
User entered '02 Oct 2020 16:57'	System	02 Oct 2020 21:57:33

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '02 Oct 2020 16:01'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 2'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:43', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:48', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:02:57', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:03:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'None (0)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:03:04', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered 'No (N)'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-03T12:03:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '67b6056b-7df3-4b46-8933-fb8dc42a9d38'	System	03 Oct 2020 17:03:09
User entered '03 Oct 2020 12:03'	System	03 Oct 2020 17:03:09

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 3'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:09', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:14', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:20', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'None (0)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered 'No (N)'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-04T16:14:29', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7f8b2685-57ac-42b5-bff7-9a3b238495ad'	System	04 Oct 2020 21:14:35
User entered '04 Oct 2020 16:14'	System	04 Oct 2020 21:14:35

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 4'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:16', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:24', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:37', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'None (0)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:43', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered 'No (N)'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-05T12:05:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '464bdd70-4bca-43b1-80d5-eb049bf3af90'	System	05 Oct 2020 17:05:53
User entered '05 Oct 2020 12:05'	System	05 Oct 2020 17:05:53

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 5'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:09', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:15', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:19', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'None (0)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:22', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered 'No (N)'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-06T12:13:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '738537fd-d71e-4fd5-a2c2-e68e3e8165d7'	System	06 Oct 2020 17:13:30
User entered '06 Oct 2020 12:13'	System	06 Oct 2020 17:13:30

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 6'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:55', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:57', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:04:59', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:05:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:05:09', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'None (0)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:05:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered 'No (N)'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-07T12:05:20', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1d4aaa0e-6931-42ea-9e68-da9f97e2f371'	System	07 Oct 2020 17:05:24
User entered '07 Oct 2020 12:05'	System	07 Oct 2020 17:05:24

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
Data entry locked.	System	02 Oct 2020 17:46:18
User entered 'Day 7'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:24:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:03', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:04', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:06', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:08', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'None (0)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:11', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered 'No (N)'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-10-08T18:25:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'b0215f94-f551-45fe-8648-da066c97709b'	System	08 Oct 2020 23:25:16
User entered '08 Oct 2020 18:25'	System	08 Oct 2020 23:25:16

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 17:46:18

US3572181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:18:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:28
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 17:46:18

US3572181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Oct 2020 18:08:14

US3572181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '9 Oct 2020'	(b) (4) (u) (4), (b) (6)	09 Oct 2020 18:08:14

US3572181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	09 Oct 2020 18:08:14

US3572181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Oct 2020 18:08:14

US3572181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Oct 2020 18:08:45

US3572181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	09 Oct 2020 18:08:45

US3572181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4) System	04 Feb 2021 02:34:02
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	04 Feb 2021 02:32:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 21:00:48

US3572181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	04 Feb 2021 02:33:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	04 Feb 2021 02:32:57
User entered '16 Oct 2020'	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 21:00:48

US3572181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	04 Feb 2021 02:34:02
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alisha Lutat (b) (4)	04 Feb 2021 02:33:11
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	16 Oct 2020 21:00:48

US3572181

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System (b) (4)	04 Feb 2021 02:34:15
Please review and reconcile.' (Site from System).		
User entered 'Safety unable to reach pt' reason for change: Data Entry Error	Alisha Lutat (b) (4)	04 Feb 2021 02:34:15
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System (b) (4)	04 Feb 2021 02:34:02
Please review and reconcile.' (Site from System).		
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	04 Feb 2021 02:33:11
Please review and reconcile.' (Site from System).		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	16 Oct 2020 21:00:48
Please review and reconcile.' (Site from System).		
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 21:00:48

US3572181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:18

US3572181

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	23 Oct 2020 14:51:18

US3572181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:30

US3572181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered '23 Oct 2020'	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:30

US3572181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:30

US3572181

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered empty.	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:30

US3572181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:28
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	23 Oct 2020 14:51:35

US3572181

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	23 Oct 2020 14:51:35

US3572181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:55:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:55:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:55:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'VISIT3'	System	04 Nov 2020 19:55:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '16:35'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Nov 2020 16:35'	System	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '95'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'bpm'	System	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '18'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'breaths/min'	System	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '137'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '94'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'mmHg'	System	04 Nov 2020 19:56:44

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54

US3572181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:11

US3572181

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:11

US3572181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:24

US3572181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '02 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:24

US3572181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered '16:46'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:24

US3572181

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered '02 Nov 2020 16:46'	System	04 Nov 2020 19:57:24

US3572181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 00:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 19:57:30

US3572181

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'I'	System	04 Nov 2020 19:57:30

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 64'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-11-03T04:27:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8556b372-1d2d-4a82-a3e0-48bc671156a0'	System	03 Nov 2020 10:28:07
User entered 'No (N)'	System	03 Nov 2020 10:28:07

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-11-03T04:27:53', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8556b372-1d2d-4a82-a3e0-48bc671156a0'	System	03 Nov 2020 10:28:07
User entered 'No (N)'	System	03 Nov 2020 10:28:07

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-11-03T04:28:01', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '8556b372-1d2d-4a82-a3e0-48bc671156a0' User entered '03 Nov 2020 04:28:01'	System	03 Nov 2020 10:28:07
	System	03 Nov 2020 10:28:07

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 03:34:32
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 71'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered 'Day 78'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:35:32

US3572181

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:32:40
Data entry locked.	System	03 Sep 2020 19:35:32
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:35:32

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-11-24T14:07:13', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2cef11e5-7df5-438a-91e6-a1719096a257'	System	24 Nov 2020 20:07:58
User entered 'No (N)'	System	24 Nov 2020 20:07:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-11-24T14:07:23', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2cef11e5-7df5-438a-91e6-a1719096a257'	System	24 Nov 2020 20:07:58
User entered 'Yes (Y)'	System	24 Nov 2020 20:07:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Please 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 (45fa0759b1d765bc)', Time: '2020-11-24T14:07:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2cef11e5-7df5-438a-91e6-a1719096a257'	System	24 Nov 2020 20:07:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Nov 2020 20:07:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-11-24T14:07:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2cef11e5-7df5-438a-91e6-a1719096a257' User entered '24 Nov 2020 14:07:47'	System	24 Nov 2020 20:07:58
	System	24 Nov 2020 20:07:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-01T12:18:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e6eaf96a-d817-49ae-9ee4-556a9792485d'	System	01 Dec 2020 18:18:52
User entered 'No (N)'	System	01 Dec 2020 18:18:52

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-12-01T12:18:46', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e6eaf96a-d817-49ae-9ee4-556a9792485d'	System	01 Dec 2020 18:18:52
User entered 'No (N)'	System	01 Dec 2020 18:18:52

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-12-01T12:18:50', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'e6eaf96a-d817-49ae-9ee4-556a9792485d' User entered '01 Dec 2020 12:18:50'	System	01 Dec 2020 18:18:52
	System	01 Dec 2020 18:18:52

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-05T04:32:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered 'Yes (Y)'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-12-05T04:32:10', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered 'Yes (Y)'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 (45fa0759b1d765bc)', Time: '2020-12-05T04:32:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-05T04:32:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered 'No (N)'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-05T04:32:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered 'No (N)'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-12-05T04:33:07', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'c3f8032a-12b5-4eac-8f63-d20dc89ce21d'	System	05 Dec 2020 10:33:17
User entered '05 Dec 2020 04:33:07'	System	05 Dec 2020 10:33:17

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-14T18:27:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '861b3338-1754-4e54-8677-41f8ad1f0315'	System	15 Dec 2020 00:27:45
User entered 'No (N)'	System	15 Dec 2020 00:27:45

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-12-14T18:27:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '861b3338-1754-4e54-8677-41f8ad1f0315'	System	15 Dec 2020 00:27:45
User entered 'No (N)'	System	15 Dec 2020 00:27:45

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-12-14T18:27:40', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '861b3338-1754-4e54-8677-41f8ad1f0315' User entered '14 Dec 2020 18:27:40'	System	15 Dec 2020 00:27:45
	System	15 Dec 2020 00:27:45

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-19T22:05:14', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '941c1ea5-f165-43f4-8fab-bd9db8dcc99d'	System	20 Dec 2020 04:05:51
User entered 'No (N)'	System	20 Dec 2020 04:05:51

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-12-19T22:05:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '941c1ea5-f165-43f4-8fab-bd9db8dcc99d'	System	20 Dec 2020 04:05:51
User entered 'Yes (Y)'	System	20 Dec 2020 04:05:51

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Please 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 (45fa0759b1d765bc)', Time: '2020-12-19T22:05:38', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '941c1ea5-f165-43f4-8fab-bd9db8dcc99d'	System	20 Dec 2020 04:05:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 04:05:51

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-12-19T22:05:41', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '941c1ea5-f165-43f4-8fab-bd9db8dcc99d' User entered '19 Dec 2020 22:05:41'	System	20 Dec 2020 04:05:51
	System	20 Dec 2020 04:05:51

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2020-12-26T07:48:14', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '805700af-3c7e-4fe6-b7c6-b4c7558b2d90'	System	26 Dec 2020 13:48:37
User entered 'No (N)'	System	26 Dec 2020 13:48:37

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2020-12-26T07:48:27', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '805700af-3c7e-4fe6-b7c6-b4c7558b2d90'	System	26 Dec 2020 13:48:37
User entered 'No (N)'	System	26 Dec 2020 13:48:37

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2020-12-26T07:48:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '805700af-3c7e-4fe6-b7c6-b4c7558b2d90'	System	26 Dec 2020 13:48:37
User entered '26 Dec 2020 07:48:32'	System	26 Dec 2020 13:48:37

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-02T08:21:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2e18fd0e-794b-477f-9ce3-418cdc57070a'	System	02 Jan 2021 14:22:00
User entered 'No (N)'	System	02 Jan 2021 14:22:00

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-01-02T08:21:53', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2e18fd0e-794b-477f-9ce3-418cdc57070a'	System	02 Jan 2021 14:22:00
User entered 'No (N)'	System	02 Jan 2021 14:22:00

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-01-02T08:21:55', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '2e18fd0e-794b-477f-9ce3-418cdc57070a'	System	02 Jan 2021 14:22:00
User entered '02 Jan 2021 08:21:55'	System	02 Jan 2021 14:22:00

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-09T04:30:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd4740162-57e5-45f8-a058-e9f00e0f584d'	System	09 Jan 2021 10:30:44
User entered 'No (N)'	System	09 Jan 2021 10:30:44

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-01-09T04:30:37', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd4740162-57e5-45f8-a058-e9f00e0f584d'	System	09 Jan 2021 10:30:44
User entered 'No (N)'	System	09 Jan 2021 10:30:44

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-01-09T04:30:40', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd4740162-57e5-45f8-a058-e9f00e0f584d' User entered '09 Jan 2021 04:30:40'	System	09 Jan 2021 10:30:44
	System	09 Jan 2021 10:30:44

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-16T04:31:26', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7ced3c77-d47d-4215-b640-94b4708ebb43'	System	16 Jan 2021 10:31:40
User entered 'No (N)'	System	16 Jan 2021 10:31:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-01-16T04:31:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7ced3c77-d47d-4215-b640-94b4708ebb43'	System	16 Jan 2021 10:31:40
User entered 'No (N)'	System	16 Jan 2021 10:31:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-01-16T04:31:36', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '7ced3c77-d47d-4215-b640-94b4708ebb43'	System	16 Jan 2021 10:31:40
User entered '16 Jan 2021 04:31:36'	System	16 Jan 2021 10:31:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-23T10:16:47', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '83281d64-6ea4-4cbc-97ab-82b03dbeb9ae'	System	23 Jan 2021 16:16:58
User entered 'No (N)'	System	23 Jan 2021 16:16:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-01-23T10:16:52', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '83281d64-6ea4-4cbc-97ab-82b03dbeb9ae'	System	23 Jan 2021 16:16:58
User entered 'No (N)'	System	23 Jan 2021 16:16:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-01-23T10:16:54', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '83281d64-6ea4-4cbc-97ab-82b03dbeb9ae' User entered '23 Jan 2021 10:16:54'	System	23 Jan 2021 16:16:58
	System	23 Jan 2021 16:16:58

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-30T04:32:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered 'Yes (Y)'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-01-30T04:32:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered 'No (N)'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-30T04:32:35', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered 'No (N)'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-01-30T04:32:49', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered 'Yes (Y)'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Please 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 (45fa0759b1d765bc)', Time: '2021-01-30T04:32:58', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-01-30T04:33:02', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '71adcc34-a107-4264-bced-b7d4729d3d32'	System	30 Jan 2021 10:33:13
User entered '30 Jan 2021 04:33:02'	System	30 Jan 2021 10:33:13

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-02-06T18:58:12', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16c153d3-ebb8-448a-af17-5264050b5557'	System	07 Feb 2021 00:58:25
User entered 'No (N)'	System	07 Feb 2021 00:58:25

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-02-06T18:58:17', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16c153d3-ebb8-448a-af17-5264050b5557'	System	07 Feb 2021 00:58:25
User entered 'No (N)'	System	07 Feb 2021 00:58:25

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-06T18:58:21', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '16c153d3-ebb8-448a-af17-5264050b5557'	System	07 Feb 2021 00:58:25
User entered '06 Feb 2021 18:58:21'	System	07 Feb 2021 00:58:25

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-02-13T09:58:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c7a0e22-d5fe-4391-b67c-da3e4544cbd3'	System	13 Feb 2021 15:58:40
User entered 'No (N)'	System	13 Feb 2021 15:58:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-02-13T09:58:33', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c7a0e22-d5fe-4391-b67c-da3e4544cbd3'	System	13 Feb 2021 15:58:40
User entered 'No (N)'	System	13 Feb 2021 15:58:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-13T09:58:36', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c7a0e22-d5fe-4391-b67c-da3e4544cbd3' User entered '13 Feb 2021 09:58:36'	System	13 Feb 2021 15:58:40
	System	13 Feb 2021 15:58:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-02-20T15:37:28', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd99fd38f-0095-40f1-920f-06644ee6ba38'	System	20 Feb 2021 21:37:39
User entered 'No (N)'	System	20 Feb 2021 21:37:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-02-20T15:37:32', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd99fd38f-0095-40f1-920f-06644ee6ba38'	System	20 Feb 2021 21:37:39
User entered 'No (N)'	System	20 Feb 2021 21:37:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-20T15:37:34', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'd99fd38f-0095-40f1-920f-06644ee6ba38'	System	20 Feb 2021 21:37:39
User entered '20 Feb 2021 15:37:34'	System	20 Feb 2021 21:37:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-02-28T21:28:35-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'be628ea5-7a99-4264-90a6-c6356bbba3b7'	System	01 Mar 2021 03:28:46
User entered 'No (N)'	System	01 Mar 2021 03:28:46

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-02-28T21:28:39-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'be628ea5-7a99-4264-90a6-c6356bbba3b7'	System	01 Mar 2021 03:28:46
User entered 'No (N)'	System	01 Mar 2021 03:28:46

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-28T21:28:41-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'be628ea5-7a99-4264-90a6-c6356bbba3b7' User entered '28 Feb 2021 21:28:41'	System	01 Mar 2021 03:28:46

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-03-07T21:29:26-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '06558d82-db94-4fe0-b560-c0881ed982ce' User entered 'No (N)'	System	08 Mar 2021 03:29:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-03-07T21:29:30-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '06558d82-db94-4fe0-b560-c0881ed982ce'	System	08 Mar 2021 03:29:39
User entered 'No (N)'	System	08 Mar 2021 03:29:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-03-07T21:29:33-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '06558d82-db94-4fe0-b560-c0881ed982ce'	System	08 Mar 2021 03:29:39
User entered '07 Mar 2021 21:29:33'	System	08 Mar 2021 03:29:39

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-03-13T07:13:18-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'fe0358b1-768c-4ec3-8c39-7b50fc239e02'	System	13 Mar 2021 13:13:38
User entered 'No (N)'	System	13 Mar 2021 13:13:38

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-03-13T07:13:26-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'fe0358b1-768c-4ec3-8c39-7b50fc239e02'	System	13 Mar 2021 13:13:38
User entered 'No (N)'	System	13 Mar 2021 13:13:38

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-03-13T07:13:31-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'fe0358b1-768c-4ec3-8c39-7b50fc239e02'	System	13 Mar 2021 13:13:38
User entered '13 Mar 2021 07:13:31'	System	13 Mar 2021 13:13:38

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-03-23T06:51:04-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '98b3a78a-6754-4622-8d5c-b8926f0ff0d7'	System	23 Mar 2021 11:51:14
User entered 'No (N)'	System	23 Mar 2021 11:51:14

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-03-23T06:51:08-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '98b3a78a-6754-4622-8d5c-b8926f0ff0d7'	System	23 Mar 2021 11:51:14
User entered 'No (N)'	System	23 Mar 2021 11:51:14

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-03-23T06:51:10-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '98b3a78a-6754-4622-8d5c-b8926f0ff0d7'	System	23 Mar 2021 11:51:14
User entered '23 Mar 2021 06:51:10'	System	23 Mar 2021 11:51:14

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-03-30T07:22:37-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ae58b205-1f7a-4e4b-bd76-3f0a68efab38'	System	30 Mar 2021 12:22:48
User entered 'No (N)'	System	30 Mar 2021 12:22:48

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-03-30T07:22:41-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ae58b205-1f7a-4e4b-bd76-3f0a68efab38'	System	30 Mar 2021 12:22:48
User entered 'No (N)'	System	30 Mar 2021 12:22:48

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-03-30T07:22:44-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'ae58b205-1f7a-4e4b-bd76-3f0a68efab38' User entered '30 Mar 2021 07:22:44'	System	30 Mar 2021 12:22:48
	System	30 Mar 2021 12:22:48

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-04-03T07:25:53-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9174496c-f556-4cd3-a9e9-01155fe3dd4f' User entered 'No (N)'	System	03 Apr 2021 12:26:05
	System	03 Apr 2021 12:26:05

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-04-03T07:25:58-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9174496c-f556-4cd3-a9e9-01155fe3dd4f' User entered 'No (N)'	System	03 Apr 2021 12:26:05

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-04-03T07:26:01-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '9174496c-f556-4cd3-a9e9-01155fe3dd4f' User entered '03 Apr 2021 07:26:01'	System	03 Apr 2021 12:26:05
	System	03 Apr 2021 12:26:05

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-04-10T04:44:24-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c4a3f17-75f4-41e1-8fab-b61c030dc3bb' User entered 'No (N)'	System	10 Apr 2021 09:44:34

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-04-10T04:44:27-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c4a3f17-75f4-41e1-8fab-b61c030dc3bb' User entered 'No (N)'	System	10 Apr 2021 09:44:34

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-04-10T04:44:30-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '5c4a3f17-75f4-41e1-8fab-b61c030dc3bb' User entered '10 Apr 2021 04:44:30'	System	10 Apr 2021 09:44:34
	System	10 Apr 2021 09:44:34

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-04-17T20:33:53-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4c6e1d96-498d-4dbe-aebb-163b4bcaaf4'	System	18 Apr 2021 01:34:07
User entered 'No (N)'	System	18 Apr 2021 01:34:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-04-17T20:34:00-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4c6e1d96-498d-4dbb-aebb-163b4bca1f4'	System	18 Apr 2021 01:34:07
User entered 'No (N)'	System	18 Apr 2021 01:34:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-04-17T20:34:03-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '4c6e1d96-498d-4dbb-aebb-163b4bca1f4'	System	18 Apr 2021 01:34:07
User entered '17 Apr 2021 20:34:03'	System	18 Apr 2021 01:34:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-04-25T17:55:50-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1f3e0013-3ac8-4d7d-940c-1609d913bb92'	System	25 Apr 2021 22:56:02
User entered 'No (N)'	System	25 Apr 2021 22:56:02

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-04-25T17:55:55-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1f3e0013-3ac8-4d7d-940c-1609d913bb92'	System	25 Apr 2021 22:56:02
User entered 'No (N)'	System	25 Apr 2021 22:56:02

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-04-25T17:55:58-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: '1f3e0013-3ac8-4d7d-940c-1609d913bb92'	System	25 Apr 2021 22:56:02
User entered '25 Apr 2021 17:55:58'	System	25 Apr 2021 22:56:02

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[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 (45fa0759b1d765bc)', Time: '2021-05-01T07:15:52-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'bc2cb377-6e9c-4def-ac84-d8e8a204bd5c'	System	01 May 2021 12:16:07
User entered 'No (N)'	System	01 May 2021 12:16:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Have you been exposed to someone with 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 (45fa0759b1d765bc)', Time: '2021-05-01T07:15:57-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'bc2cb377-6e9c-4def-ac84-d8e8a204bd5c'	System	01 May 2021 12:16:07
User entered 'No (N)'	System	01 May 2021 12:16:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-05-01T07:16:00-05:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'bc2cb377-6e9c-4def-ac84-d8e8a204bd5c'	System	01 May 2021 12:16:07
User entered '01 May 2021 07:16:00'	System	01 May 2021 12:16:07

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:32:40

US3572181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:18:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:32:40
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:32:40

US3572181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:18:29

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 16:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-28T21:28:08-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a40fc34b-5af3-4dc5-81bd-a26f509d14e9'	System	01 Mar 2021 03:28:21
User entered 'No (N)'	System	01 Mar 2021 03:28:21

US3572181

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:18:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 16:33:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (45fa0759b1d765bc)', Time: '2021-02-28T21:28:15-06:00', User OID: 'PatientReportedOutcome (US3572181)', ODM File OID: 'a40fc34b-5af3-4dc5-81bd-a26f509d14e9'	System	01 Mar 2021 03:28:21
User entered '28 Feb 2021 21:28:15'	System	01 Mar 2021 03:28:21

US3572181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:02
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:32:51

US3572181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:02
User entered '24 Nov 2020'	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:32:51

US3572181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:32:51

US3572181

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:02
User entered empty.	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:32:51

US3572181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User signature succeeded.	Milton Haber (b) (4)	21 Mar 2021 04:18:02
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	24 Nov 2020 16:32:59

US3572181

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 06:14:54
User entered 'l'	System	24 Nov 2020 16:32:59

US3572181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:40:39

US3572181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '31 Dec 2020'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:40:39

US3572181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:40:39

US3572181

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:40:39

US3572181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:40:44

US3572181

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered 'l'	System	31 Dec 2020 15:40:44

US3572181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 16:56:14

US3572181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '29 Jan 2021'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 16:56:14

US3572181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 16:56:14

US3572181

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (u) (4), (b) (6)	05 Feb 2021 16:56:14

US3572181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	05 Feb 2021 16:56:26

US3572181

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered 'l'	System	05 Feb 2021 16:56:26

US3572181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 18:52:51

US3572181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '26 Feb 2021'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 18:52:51

US3572181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	26 Feb 2021 18:52:51

US3572181

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (u) (4), (b) (6)	26 Feb 2021 18:52:51

US3572181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:48:41
User entered 'No (N)' reason for change: Data Entry Error	Maria Candelario (b) (4)	12 Mar 2021 16:36:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:52:57

US3572181

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered 'l'	System	23 Mar 2021 15:48:41
User entered empty.	System	12 Mar 2021 16:36:33
User entered 'l'	System	26 Feb 2021 18:52:57

US3572181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:48:58

US3572181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:48:58

US3572181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:48:58

US3572181

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered 'VISIT4'	System	23 Mar 2021 15:48:58

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered empty.	System	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered empty.	System	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Maria Candelario (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered empty.	System	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered empty.	System	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47
User entered empty.	Maria Candelario (b) (4) (b) (4)	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered empty.	System	30 Mar 2021 21:51:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34

US3572181

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:18:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34

US3572181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:15

US3572181

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:15

US3572181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:29

US3572181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '23 Mar 2021'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:29

US3572181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '09:04'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:29

US3572181

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered '23 Mar 2021 09:04'	System	23 Mar 2021 15:49:29

US3572181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 15:49:33

US3572181

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:33:34
User entered 'l'	System	23 Mar 2021 15:49:33

US3572181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:16:59

US3572181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '27 Apr 2021'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:16:59

US3572181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:16:59

US3572181

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:16:59

US3572181

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:17:04

US3572181

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Apr 2021 15:17:04

US3572181

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:04:51

US3572181

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:04:51

US3572181

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[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 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:04:51

US3572181

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

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'UNBLND_DECIDE'	System	01 Mar 2021 23:04:51

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:10
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:39:41

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	10 Mar 2021 23:58:10
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	10 Mar 2021 23:58:10
	System	06 Mar 2021 14:39:41

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	13 Apr 2021 04:33:09
User closed query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4)	
Query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' answered with 'updated per source' (Site from DM).	(u) (4), (b) (6)	12 Apr 2021 09:48:23
Signature has been broken.	Caitlin roll (b) (4)	08 Apr 2021 20:18:21
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Caitlin roll (b) (4)	08 Apr 2021 20:17:38
User opened query 'Per IRT this subject was randomized to placebo treatment assignment. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:15:57
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	
	(u) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'I'	System	01 Mar 2021 23:06:01

US3572181

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

Form: Unblinding

Generated On: 10 Jun 2021 08:18:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'I'	System	01 Mar 2021 23:06:01

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered empty.	System	11 Mar 2021 00:02:42
DataPoint set to visible.	System	01 Mar 2021 23:06:01

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered empty.	System	11 Mar 2021 00:02:42
DataPoint set to visible.	System	01 Mar 2021 23:06:01

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '14:00'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered '10 Mar 2021 14:00'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '110'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'bpm'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '18'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'breaths/min'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '133'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'mmHg'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '89'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'mmHg'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:18:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered empty.	System	11 Mar 2021 00:02:42
DataPoint set to visible.	System	01 Mar 2021 23:06:01

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '15:35'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered '10 Mar 2021 15:35'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'TEMPORAL'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '107'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'bpm'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '19'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'breaths/min'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '121'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'mmHg'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '83'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:02:42

US3572181

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'mmHg'	System	11 Mar 2021 00:02:42

US3572181

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:15

US3572181

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:15

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'mRNA-1273'	System	10 Mar 2021 23:58:53
DataPoint set to visible.	System	01 Mar 2021 23:06:01

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '14:59'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered '10 Mar 2021 14:59'	System	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'ONCE'	System	10 Mar 2021 23:58:53

US3572181

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

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 23:58:53

US3572181

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:14

US3572181

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:14

US3572181

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '15:33'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:14

US3572181

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:18:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered '1 Mar 2021 15:33'	System	01 Mar 2021 23:06:14

US3572181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:25

US3572181

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '1 Mar 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:25

US3572181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '15:29'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 23:06:25

US3572181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:18:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered '1 Mar 2021 15:29'	System	01 Mar 2021 23:06:25

US3572181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Mar 2021 16:28:26

US3572181

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:20:39
User entered 'I'	System	09 Mar 2021 16:28:26

US3572181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	17 Mar 2021 14:14:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 10:54:17
Query 'Data is required. Please complete.' answered with 'Subject came in for dose 1 on 10Mar2021' (Site from System).	(b) (4), (b) (6)	12 Mar 2021 23:37:56
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 23:36:55
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 23:36:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 23:36:55
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 23:36:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 16:30:03

US3572181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '17 Mar 2021' reason for change: New Information	(b) (4)	17 Mar 2021 14:14:07
User closed query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(u) (4), (b) (6)	17 Mar 2021 14:14:07
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	12 Mar 2021 23:36:22
Query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	12 Mar 2021 23:36:22
User closed query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	12 Mar 2021 23:36:22
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	12 Mar 2021 23:36:22
User opened query 'OL Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Participant Decision Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Mar 2021 23:58:53
User opened query 'The 'Date of Contact or Contact Attempt' is before the 'Date of updated Informed Consent'. Please review and reconcile.' (Site from System).	System	09 Mar 2021 16:30:03
User entered '22 Jan 2021'	(b) (4), (b) (6)	09 Mar 2021 16:30:03

US3572181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4) (u) (4), (b) (6)	17 Mar 2021 14:14:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 23:36:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 16:30:03

US3572181

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (u) (4), (b) (6)	09 Mar 2021 16:30:03

US3572181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	09 Mar 2021 16:30:41

US3572181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User entered 'l'	System	09 Mar 2021 16:30:41

US3572181

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:51:22
User entered 'I'	System	09 Mar 2021 16:30:41
DataPoint set to visible.	System	09 Mar 2021 16:30:41

US3572181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:33:06

US3572181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:33:06

US3572181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered 'Clinic (Clinic)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:33:06

US3572181

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:18:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	16 Apr 2021 17:33:06

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '14:42'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 14:42'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '97.9' F	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '100'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '18'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '117'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '81'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '16:00'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 16:00'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '98.1' F	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Other (Other)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'temporal'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '99'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '18'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '137'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '89'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:18:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Apr 2021 17:37:08

US3572181

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:43:42

US3572181

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:18:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:43:42

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 11:29:38
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered with 'updated' (Site from System).	Milton Haber (b) (4) (b) (4) (u) (4), (b) (6)	19 Apr 2021 05:00:14
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	16 Apr 2021 17:45:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	16 Apr 2021 17:45:38
DataPoint set to visible.	System	09 Mar 2021 16:30:41

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered '8 Apr 2021'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered empty.	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) (u) (4), (b) (6)	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:18:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Apr 2021 17:45:38

US3572181

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:17

US3572181

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Apr 2021 21:34:17

US3572181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:28

US3572181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered '15 Apr 2021'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:28

US3572181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:28

US3572181

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:18:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered empty.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:28

US3572181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:24
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:32

US3572181

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:18:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Apr 2021 21:34:32

US3572181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:17:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 15:17:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 23:12:06
User closed query 'Please update to Yes, as subject did have an SAE and AEs noted in source and documented in EDC (AM)' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 23:11:52
Query 'Please update to Yes, as subject did have an SAE and AEs noted in source and documented in EDC (AM)' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:37:36
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 22:36:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 22:36:40
User opened query 'Please update to Yes, as subject did have an SAE and AEs noted in source and documented in EDC (AM)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:06:40
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
Signature has been broken.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:34:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User closed query ' <input type="checkbox"/> Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4) (u) (4), (b) (6)	26 Mar 2021 10:39:23
Query ' <input type="checkbox"/> Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly.' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:53:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Mar 2021 05:53:41

US3572181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query ' Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:52:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 16:30:49
User closed query ' <input type="checkbox"/> Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 05:13:22
Query ' <input type="checkbox"/> Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:36:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Mar 2021 05:36:45
User opened query ' <input type="checkbox"/> Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:17:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Feb 2021 18:53:10
User closed query 'Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 04:58:49
Query 'Per CDM: “Did participant experience any adverse event” recorded as “No” however, adverse events are recorded on corresponding page. Please review and update accordingly.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 22:23:09
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 22:22:58

US3572181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:18:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: "Did participant experience any adverse event" recorded as "No" however, adverse events are recorded on corresponding page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 04:47:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 16:56:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 00:51:47
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:03:05

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	12 Feb 2021 09:26:18
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 12:07:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 12:07:45
Data point term sent to Coder	System	08 Feb 2021 23:47:57
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 23:47:27
Coding entries removed.	(b) (4), (b) (6)	08 Feb 2021 23:47:15
User entered 'Acute exacerbation of HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 23:47:15
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure grade is more than 1/Mild. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 05:15:31

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 00:56:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Jan 2021 00:56:36
Data point term sent to Coder	System	06 Jan 2021 00:55:12
User entered 'Hypertension'	(b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '14:17'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
User entered '03 Sep 2020 14:17'	System	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '15:08'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
User entered '03 Sep 2020 15:08'	System	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 04:49:16
Query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 00:47:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 00:47:01
User opened query 'Per DM CLR: Please review Severity and please note, worsening event is expected to have a severity that is greater than Grade 1/Mild. Please review and update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:56:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'l'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (u) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
User entered '0'	System	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48
User entered '0'	System	06 Jan 2021 00:54:39

US3572181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:56:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 14:33:09
User entered 'USA-US091-2021-mRNA-1273-P301000008'	System	03 Feb 2021 14:13:43
User entered 'New'	(b) (4), (b) (6)	03 Feb 2021 14:13:43

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'For coding purposes, HYSTERECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4) (b) (4), (b) (6)	14 Mar 2021 20:47:46
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Fibroids - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 22:41:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Feb 2021 22:41:45
Query 'For coding purposes, HYSTERECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' answered with 'updated to indicate underlying condition that led to elective hysterectomy' (Site from Coder).	(b) (4), (b) (6)	02 Feb 2021 05:10:57
Data point term sent to Coder	System	02 Feb 2021 05:10:51
Coding entries removed.	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User entered 'Multiple Fibroids' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User opened query 'For coding purposes, HYSTERECTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	01 Feb 2021 10:55:32
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 02:19:10

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	29 Jan 2021 02:19:10
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 02:18:59
User entered 'Hysterectomy'	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User entered 'No (N)'	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '27 Jan 2021'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4) System	02 Feb 2021 05:11:37
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Feb 2021 05:11:37
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Feb 2021 05:10:23
User entered '27 Jan 2021'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

Severity

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 05:10:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 05:10:23
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 02:18:48
User entered empty.	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Feb 2021 05:10:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 05:10:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 02:18:48
User entered empty.	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	02 Feb 2021 05:12:21
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	02 Feb 2021 05:12:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 02:18:48
User entered 'I'	Maria Candelario (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '27 Jan 2021'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 05:12:21
	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'Not Related (NOT RELATED)'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable, for the event of multiple fibroids.' (Site from Safety).	(b) (4) (u) (4), (b) (6)	17 Feb 2021 14:32:54
Query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable, for the event of multiple fibroids.' answered with 'updated' (Site from Safety).	Caitlin roll (b) (4)	16 Feb 2021 19:41:11
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 19:41:05
User opened query 'PV Query: As the last dose of study drug was given on 02 Oct 2020, please update the action taken with study drug from none to not applicable, for the event of multiple fibroids.' (Site from Safety).	(u) (4), (b) (6)	12 Feb 2021 14:16:11
User entered 'None (NONE)'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

None

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	02 Feb 2021 05:10:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Jan 2021 02:18:48
User entered '0'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 04:50:38
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' answered with 'hysterectomy added to Con Procedure eCRF' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 00:54:18
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded therapeutic procedure that match this AE within this time frame. Please update to record the treatment procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:57:14
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 05:10:23
User entered '0'	Maria Candelario (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	02 Feb 2021 05:11:37
Data Entry Error	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 05:10:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Feb 2021 05:10:23
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	(b) (4), (b) (6)	02 Feb 2021 05:10:23
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 02:18:48
User entered empty.	Maria Candelario (b) (4)	29 Jan 2021 02:18:48
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:21:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'Subject reported scheduled hysterectomy, initial report. pending medical records'	Maria Candelario (b) (4) (b) (4)	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	02 Feb 2021 05:10:23

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Feb 2021 05:10:23
User entered '0'	System	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 02:18:48

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 15:31:26
User entered 'USA-US091-2021-mRNA-1273-P301000008'	(b) (4), (b) (6)	10 Feb 2021 15:31:06

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural fever, LLT: Post procedural fever - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 22:16:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 22:16:41
Data point term sent to Coder	System	09 Feb 2021 20:44:18
User entered 'Fever Post Hysterectomy' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:43:39
Data point term sent to Coder	System	09 Feb 2021 20:13:24
User entered 'Prolonged Hospitalization Due to Fever'	Maria Candelario (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'Yes (Y)'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)'	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '27 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:25:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 20:19:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 20:19:31
User entered '30 Jan 2021' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 20:12:35
User entered empty.	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
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	09 Feb 2021 20:19:31
User entered 'No (N)' reason for change: Data Entry Error	System	09 Feb 2021 20:19:31
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	09 Feb 2021 20:19:31
User entered empty.	(b) (4)	
	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	
User entered '30 Jan 2021' reason for change: Data Entry Error	System	09 Feb 2021 20:33:14
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	Maria Candelario (b) (4)	09 Feb 2021 20:33:14
User entered empty.	(b) (4)	
	System	09 Feb 2021 20:19:31
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'PV Query: Please provide the event severity for fever post hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:34:35
Query 'PV Query: Please provide the event severity for fever post hysterectomy.' answered with 'It is grade 2/moderate' (Site from Safety).	Caitlin roll (b) (4)	16 Feb 2021 19:42:06
User opened query 'PV Query: Please provide the event severity for fever post hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 14:17:15
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Feb 2021 21:20:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Feb 2021 21:20:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 21:20:51
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 20:12:35
User entered empty.	Maria Candelario (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
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	09 Feb 2021 21:39:18
User entered 'Yes (Y)' reason for change: Data Entry Error	System	09 Feb 2021 21:39:18
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	09 Feb 2021 21:39:18
User entered empty.	(b) (4)	
	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Mar 2021 22:10:03
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Mar 2021 22:10:03
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Feb 2021 19:46:08
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 02:57:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'The subject was not admitted in ICU' (Site from System).	Maria Candelario (b) (4)	09 Feb 2021 20:32:39
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	09 Feb 2021 20:24:33
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:24:33
User entered '0'	Maria Candelario (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
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)	19 Mar 2021 13:35:58
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 'Not Done' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	18 Mar 2021 19:57:17
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)	10 Mar 2021 17:12:17
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:46:35
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'DATES UPDATED' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 22:10:16
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 22:09:32

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
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. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety). User entered empty.	(b) (4), (b) (6) Maria Candelario (b) (4) (b) (4)	19 Feb 2021 18:54:48 09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 13:36:05
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Pending redaction' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	18 Mar 2021 19:58:13
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 18:55:08
User closed query '(fever post hysterectomy): PV Query: It was reported that the subject's initial hospitalization was due to multiple fibroids. Please confirm if the event of fever post hysterectomy caused prolongation of hospital stay Also, please confirm the subject was discharged from the hospital on 28 Jan 2021.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:34:41

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query '(fever post hysterectomy): PV Query: It was reported that the subject's initial hospitalization was due to multiple fibroids. Please confirm if the event of fever post hysterectomy caused prolongation of hospital stay Also, please confirm the subject was discharged from the hospital on 28 Jan 2021.' answered with 'UPDATED' (Site from Safety). User entered '03 Feb 2021' reason for change: Data Entry Error	Caitlin roll (b) (4)	16 Feb 2021 19:46:20
User opened query '(fever post hysterectomy): PV Query: It was reported that the subject's initial hospitalization was due to multiple fibroids. Please confirm if the event of fever post hysterectomy caused prolongation of hospital stay Also, please confirm the subject was discharged from the hospital on 28 Jan 2021.' (Site from Safety). User entered empty.	(u) (4), (b) (6)	12 Feb 2021 14:17:43
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 22:10:03
User entered empty.	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered empty.	(b) (4)	
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 20:33:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 20:33:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:33:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Feb 2021 20:33:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Feb 2021 20:33:14
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:33:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
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	09 Feb 2021 20:19:31
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	09 Feb 2021 20:19:31
User opened query 'Data is required. Please complete.' (Site from System).	Maria Candelario (b) (4)	09 Feb 2021 20:19:31
User entered empty.	(b) (4)	
	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

None

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	18 Mar 2021 19:59:33
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4)	18 Mar 2021 19:59:33
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Mar 2021 19:59:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Feb 2021 20:33:14
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Feb 2021 20:12:35
User entered '0'	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'PV Query: Please provide treatment given for the event of fever post hysterectomy. 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) (u) (4), (b) (6)	19 Mar 2021 13:36:26
Query 'PV Query: Please provide treatment given for the event of fever post hysterectomy. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Data updated' (Site from Safety).	Maria Candelario (b) (4) (b) (4)	18 Mar 2021 19:59:42
User entered '0' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	18 Mar 2021 19:59:12
User opened query 'PV Query: Please provide treatment given for the event of fever post hysterectomy. 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).	(u) (4), (u) (6)	12 Feb 2021 14:14:12
User entered '1' reason for change: Data Entry Error	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:33:14
User entered '0'	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User entered '0'	(b) (4) Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
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	09 Feb 2021 20:33:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	System	09 Feb 2021 20:33:14
Data Entry Error	Maria Candelario (b) (4)	09 Feb 2021 20:33:14
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	09 Feb 2021 20:12:35
	Maria Candelario (b) (4)	09 Feb 2021 20:12:35
	(b) (4)	

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	22 Mar 2021 03:32:25
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:21
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	22 Mar 2021 03:32:25
User closed query 'PV Query: Please provide subject's body temperature for the event of fever post hysterectomy.' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide subject's body temperature for the event of fever post hysterectomy.' answered with 'UPDATED PER MR's FINAL REPORT.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 15:52:18
User entered '@1130 CALLED THE SUBJECT TO FU ON HER RECENT SURGERY OF HYSTERECTOMY AND AT WHAT HOSPITAL AND HER DC DATE. SHE INFORMED ME SHE WAS AT THE LAREDO MEDICAL CENTER (MED RECS FAX 956-796-4228) FROM 27JAN2021 - 03FEB2021. SHE WAS KEPT AT THE HOSPITAL LONGER BECAUSE SHE DEVELOPED A FEVER. (AS OF 01/30/2021 SHE HAD A TEMP OF 99.6). SHE IS CURRENTLY HOME AND DOING WELL.' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 16:24:24
User opened query 'PV Query: Please provide subject's body temperature for the event of fever post hysterectomy.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:23:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Feb 2021 14:18:26
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Feb 2021 21:23:10
User entered '@1130 Called the subject to FU on her recent surgery of Hysterectomy and at what hospital and her DC date. She informed me she was at the Laredo medical center (Med Recs Fax 956-796-4228) from 27Jan2021 - 03Feb2021. she was kept at the hospital longer because she developed a fever. She is currently home and doing well.' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Feb 2021 21:23:10

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Feb 2021 21:39:18
User entered empty.	Maria Candelario (b) (4) (b) (4)	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 21:39:18

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Feb 2021 20:12:35

US3572181

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 22:10:03

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User coded data point as SOC: Reproductive system and breast disorders, HLT: Vulvovaginal disorders (excl infections and inflammations), HLT: Vulvovaginal disorders NEC, PT: Vaginal haemorrhage, LLT: Vaginal bleeding - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 16:50:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 16:50:00
Data point term sent to Coder	System	31 Mar 2021 16:48:57
User entered 'Vaginal bleeding'	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '21 Oct 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
User entered empty.	System	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '30 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
User entered empty.	System	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Not Related (NOT RELATED)'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47
User entered 'Not Applicable (NOT APPLICABLE)'	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'I'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Subject went on to have elective hysterectomy'	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 20:22:10
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:16:27
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
User entered '0'	System	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03
User entered 'I'	System	31 Mar 2021 16:48:36

US3572181

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:18:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:57:03

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:17:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 15:17:22
User closed query 'Please note SAE/AEs state con meds were taken by subject however are not listed in EDC. Please verify and add as appropriate (AM) Please also add medications given to subject during hysterectomy(AM)' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:24:05
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:22:38
User closed query 'per source and con med list subject has taken con meds, please correct answer to Yes (AM)' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:22:20
Query 'Please note SAE/AEs state con meds were taken by subject however are not listed in EDC. Please verify and add as appropriate (AM) Please also add medications given to subject during hysterectomy(AM)' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:43:21
Query 'per source and con med list subject has taken con meds, please correct answer to Yes (AM)' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:38:31
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 22:38:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 22:38:01
User opened query 'Please note SAE/AEs state con meds were taken by subject however are not listed in EDC. Please verify and add as appropriate (AM) Please also add medications given to subject during hysterectomy(AM)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:24:11
User opened query 'per source and con med list subject has taken con meds, please correct answer to Yes (AM)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:17:37
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
Signature has been broken.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:34:50

PRODUCTION RELEASE (v12.003
EAB) (1725)

1932 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User closed query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' (Site from DM).	(b) (4) (u) (4), (b) (6)	31 Mar 2021 04:12:31
Query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' answered with 'reviewed and updated' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 05:47:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 05:46:33
User opened query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 03:14:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 16:30:56
User closed query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.	(b) (4), (b) (6)	15 Feb 2021 13:41:24
' (Site from DM).		
Query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly.	(b) (4), (b) (6)	11 Feb 2021 21:24:13
' answered with 'updated to Yes per source documented AE's' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Feb 2021 21:24:05

PRODUCTION RELEASE (v12.003
EAB) (1725)

1933 of 2178

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:18:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No". However, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 16:20:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 16:56:53
User closed query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 05:25:13
Query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:48:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 19:48:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 15:41:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 15:41:09
User opened query 'Per CDM: Response to 'Were any prior/concomitant medications and/or vaccinations taken?' is recorded as "No"; however, data has been recorded on "Prior/Concomitant Medication and Vaccination" eCRF. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:14:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 16:33:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 15:31:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:03:13
User entered 'Yes (Y)'	Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:10:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Sep 2020 20:14:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Sep 2020 20:14:46
Data point term sent to Coder User entered 'Lisinopril'	System Alisha Lutat (b) (4)	03 Sep 2020 20:13:24 03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Hypertension'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '40'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'mg (mg)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'once daily (QD)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Oral (ORAL)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'UN UNK 2017'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) Alisha Lutat (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) Alisha Lutat (b) (4) (b) (4)	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:12:53

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
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)	23 Oct 2020 15:35:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:35:42
Data point term sent to Coder	System	23 Oct 2020 15:34:01
User entered 'Influenza vaccine'	(b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Flu prevention'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0.5'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'every year/seasonal'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	23 Oct 2020 15:33:22
User entered '16 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 15:33:22
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	23 Oct 2020 15:33:01
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:18:41
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
User entered empty.	System	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
User entered empty.	System	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:44:04
User entered empty.	System	23 Oct 2020 15:33:01

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 22:42:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 22:42:46
Data point term sent to Coder	System	20 Apr 2021 22:41:46
User entered 'Ibuprofen'	(b) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Pain at injection site'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '800'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'four times daily (QID)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '27 Jan 2021'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '0'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 22:41:02

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
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.	(b) (4) Coder Import (b) (4)	20 Apr 2021 22:44:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 22:44:46
Data point term sent to Coder	System	20 Apr 2021 22:43:48
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Hypertension'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '25'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'mg (mg)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'once daily (QD)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Oral (ORAL)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '25 Feb 2021'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered '0'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'Yes (Y)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered empty.	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
User entered 'No (N)'	(b) (4) (u) (4), (b) (6)	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:18:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 22:43:14

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:18:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	28 Apr 2021 10:09:49
DataPoint Un-verified.	(b) (4) (u) (4), (b) (6)	27 Apr 2021 15:17:29
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	27 Apr 2021 15:17:29
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:25:00
User closed query 'Subject had 2 con procedures, this question should be yes to reflect that. This was verified in source, please update as appropriate (AM)' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 18:24:47
Query 'Subject had 2 con procedures, this question should be yes to reflect that. This was verified in source, please update as appropriate (AM)' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 05:08:53
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 05:07:36
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	21 Apr 2021 05:07:36
User opened query 'Subject had 2 con procedures, this question should be yes to reflect that. This was verified in source, please update as appropriate (AM)' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:28:37
User signature succeeded.	Milton Haber (b) (4)	19 Apr 2021 05:00:14
Signature has been broken.	(b) (4) (u) (4), (b) (6)	15 Apr 2021 21:34:58
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	15 Apr 2021 21:34:58
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User closed query 'Per CDM: Were any concomitant procedures performed = No, however note that concomitant procedures were recorded. Please review and update accordingly.' (Site from DM).	(b) (4) (u) (4), (b) (6)	30 Mar 2021 10:30:57
Query 'Per CDM: Were any concomitant procedures performed = No, however note that concomitant procedures were recorded. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:15:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Mar 2021 05:15:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

2007 of 2178

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:18:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Were any concomitant procedures performed = No, however note that concomitant procedures were recorded. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:42:13
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Mar 2021 16:31:02
User closed query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedure is recorded. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 06:32:07
Query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedure is recorded. Please review and update accordingly. ' answered with 'as per query resolution' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 17:13:29
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	18 Feb 2021 17:13:18
User opened query 'Per CDM: Were any concomitant procedures performed = No, However concomitant procedure is recorded. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 09:27:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 16:56:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Dec 2020 15:41:34
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:03:21

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '2 Dec 2020'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:42:13

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Biopsy of Cervix'	(b) (4) (u) (4), (b) (6)	31 Dec 2020 15:42:13

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	11 Apr 2021 07:09:50
User closed query 'Per DM CLR-RQ: Response noted. However, procedure start date is not within the timeframe of the corresponding AE (21OCT2020 - 30NOV2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4) (u) (4), (b) (6)	06 Apr 2021 01:55:27
Query 'Per DM CLR-RQ: Response noted. However, procedure start date is not within the timeframe of the corresponding AE (21OCT2020 - 30NOV2020). Please review and reconcile date of procedure or clarify as necessary. ' answered with 'biopsy done pre-hysterectomy for diagnostic purposes not due to an AE' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:50:56
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 02:50:04
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 02:50:04
User opened query 'Per DM CLR-RQ: Response noted. However, procedure start date is not within the timeframe of the corresponding AE (21OCT2020 - 30NOV2020). Please review and reconcile date of procedure or clarify as necessary. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 19:38:29
User closed query 'Per DM CLR RQ: Please review if this Con Proc was done for SAE #2 MULTIPLE FIBROIDS (27 JAN 2021). If yes, please review the Date of this procedure as it is prior to the start date of corresponding AE. Please review and reconcile date of procedure. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 05:12:16
User signature succeeded.	Milton Haber (b) (4) (b) (4)	03 Apr 2021 04:42:47

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR RQ: Please review if this Con Proc was done for SAE #2 MULTIPLE FIBROIDS (27 JAN 2021). If yes, please review the Date of this procedure as it is prior to the start date of corresponding AE. Please review and reconcile date of procedure. Otherwise, clarify. ' answered with 'Subject states she had the biopsy as a result of ongoing vaginal bleeding which was added as an AE.' (Site from DM).	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:51:04
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	31 Mar 2021 16:02:33
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	31 Mar 2021 16:02:09
User opened query 'Per DM CLR RQ: Please review if this Con Proc was done for SAE #2 MULTIPLE FIBROIDS (27 JAN 2021). If yes, please review the Date of this procedure as it is prior to the start date of corresponding AE. Please review and reconcile date of procedure. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:37:46
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:37:46
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 23:41:13
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Mar 2021 23:41:05

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 10:00:09
User entered 'Medical History (MH)'	(b) (4), (b) (6)	31 Dec 2020 15:42:13

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:18:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
	(b) (4)	
User entered empty; reason for change Data Entry Error	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:02:33
User entered 'medical history/ to scheduled hysterectomy' reason for change: Per Query Resolution	Martha Bunnell-Pollak (b) (4)	31 Mar 2021 16:02:09
User entered empty.	(b) (4), (b) (6)	31 Dec 2020 15:42:13

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '27 Jan 2021'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 00:52:49

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Hysterectomy'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 00:52:49

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'Adverse Event (AE)'	(b) (4) (u) (4), (b) (6)	02 Mar 2021 00:52:49

US3572181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:18:29

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:04:11
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered empty.	(b) (4) (u) (4), (b) (6)	02 Mar 2021 00:52:49

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '03/Feb/2021 09:13'	(b) (4) System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'l'	(b) (4), (b) (6)	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '10/Feb/2021 10:31'	(b) (4) System	10 Feb 2021 15:31:51

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	12 Feb 2021 16:08:53
User entered 'l'	(b) (4), (b) (6)	10 Feb 2021 15:31:51

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '12/Feb/2021 11:09'	(b) (4) System	12 Feb 2021 16:09:19

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 15:53:46
User entered 'l'	(b) (4), (b) (6)	12 Feb 2021 16:09:19

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '17/Feb/2021 09:34'	(b) (4) System	17 Feb 2021 14:34:07

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 15:53:46
User entered 'l'	(b) (4), (b) (6)	17 Feb 2021 14:34:07

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '17/Feb/2021 09:35'	(b) (4) System	17 Feb 2021 14:35:10

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 15:53:46
User entered 'l'	(b) (4), (b) (6)	17 Feb 2021 14:35:10

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '02/Mar/2021 11:47'	(b) (4) System	02 Mar 2021 16:47:14

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	17 Mar 2021 15:53:46
User entered 'l'	(b) (4), (b) (6)	02 Mar 2021 16:47:14

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '17/Mar/2021 11:54'	(b) (4) System	17 Mar 2021 15:54:06

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'I'	(b) (4) (u) (4), (b) (6)	17 Mar 2021 15:54:06

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'USA-US091-2021-MRNA-1273-P301000008'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Yes (Y)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'No (N)'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Milton'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Haber'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '2344 Laguna Del Mar, Suite 201'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'Laredo'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'TX'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered '78041'	System	03 Feb 2021 14:13:43

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
Reviewed for Safety.	(b) (4) (u) (4), (b) (6)	03 Feb 2021 14:14:00
User entered 'US'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 08:18:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	19 Mar 2021 13:36:51
User entered '7'	System	17 Mar 2021 15:54:06
User entered '6'	System	02 Mar 2021 16:47:14
User entered '5'	System	17 Feb 2021 14:35:10
User entered '4'	System	17 Feb 2021 14:34:07
User entered '3'	System	12 Feb 2021 16:09:19
User entered '2'	System	10 Feb 2021 15:31:51
User entered '1'	System	03 Feb 2021 14:13:57

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:18:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered '19/Mar/2021 09:36'	(b) (4) System	19 Mar 2021 13:36:51

US3572181

Folder: SAE USA-US091-2021-MRNA-1273-P301000008

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 08:18:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:05:39
User signature succeeded.	Milton Haber (b) (4)	03 Apr 2021 04:42:47
User entered 'I'	(b) (4) (u) (4), (b) (6)	19 Mar 2021 13:36:51