

US3772041 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:48:08

All time stamps listed in this document are displayed in GMT

US3772041

Form: Participant Creation

Data signed: (b) (4) 23 Mar 2021 02:52:57

Generated On: 10 Jun 2021 09:48:08

[Participant ID](#)

US3772041

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

US3772041

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Date of Birth (MMM yyyy)	(b) (6) 1933
Age	87
Age Units	YEARS
Age (Derived)	87
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Mar 2021 00:25:03

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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)	

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

Condition	COMPLETE HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:46 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:46
Height (<i>xxx.x</i>)	149 cm
Weight (<i>xxx.x</i>)	49.5 kg
BMI (<i>xxx.x</i>)	22.29629 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Date of assessment (dd MMM yyyy) 11 AUG 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) UN UNK 1995

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Mar 2021 00:25:03

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185699

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

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)	11 AUG 2020
Time of assessment (00:00-23:59)	09:46 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:46
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

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)	11 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:00
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

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) 11 AUG 2020

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

Treatment Date and Time (derived) 11 AUG 2020 11:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 AUG 2020

Collection time (00:00-23:59)

11:05 (24 HR)

Collection date and time (derived)

11 AUG 2020 11:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:07	11 AUG 2020 11:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

96.9 °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

11 AUG 2020 12:03

PC Open Date & Time

11 AUG 2020 11:43

PC Close Date & Time

11 AUG 2020 14:13

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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	12 AUG 2020 06:19
PC Open Date & Time	11 AUG 2020 15:08
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

13 AUG 2020 06:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 06:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 05:33

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 07:19

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 06:38

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:04

PC Open Date & Time

11 AUG 2020 11:43

PC Close Date & Time

11 AUG 2020 14:13

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

12 AUG 2020 06:20

PC Open Date & Time

11 AUG 2020 15:08

PC Close Date & Time

12 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

13 AUG 2020 06:59

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

14 AUG 2020 06:03

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

15 AUG 2020 05:33

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

16 AUG 2020 07:19

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

17 AUG 2020 06:39

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

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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 ☐

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 12:05
PC Open Date & Time	11 AUG 2020 11:43
PC Close Date & Time	11 AUG 2020 14:13

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Folder: Diary Dose 1 (1)

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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 ☐

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

11 AUG 2020 15:08

PC Close Date & Time

12 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

Yes ☐

PC Time stamp

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 06:04
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 05:34
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 07:20
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 06:40
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

Yes ☐

PC Time stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3772041

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

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)	08 SEP 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 10:40
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 12:43
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3772041

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

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) 08 SEP 2020

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

Treatment Date and Time (derived) 08 SEP 2020 12:00

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

US3772041

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 SEP 2020
Collection time (00:00-23:59)	11:16 (24 HR)
Collection date and time (derived)	08 SEP 2020 11:16

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:18	08 SEP 2020 11:18
Nasopharyngeal Swab 2	No		

US3772041

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

97.7 °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

08 SEP 2020 12:45

PC Open Date & Time

08 SEP 2020 12:20

PC Close Date & Time

08 SEP 2020 14:50

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	08 SEP 2020 18:04
PC Open Date & Time	08 SEP 2020 15:45
PC Close Date & Time	09 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 18:14

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 18:10

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

12 SEP 2020 18:29

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 18:40

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

08 SEP 2020 12:46

PC Open Date & Time

08 SEP 2020 12:20

PC Close Date & Time

08 SEP 2020 14:50

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 18:04

PC Open Date & Time

08 SEP 2020 15:45

PC Close Date & Time

09 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 18:16

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

3

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

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

Yes ☒

No ☐

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:11

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 18:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 18:41

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 18:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 12:46
PC Open Date & Time	08 SEP 2020 12:20
PC Close Date & Time	08 SEP 2020 14:50

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:05
PC Open Date & Time	08 SEP 2020 15:45
PC Close Date & Time	09 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:13
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:38
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:30
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:42
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

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 ☒

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:13
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3772041

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:01

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:28
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3772041

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

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.

US3772041

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

13 OCT 2020 08:35

US3772041

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:37:07

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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	14 OCT 2020 13:39:36
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 16:33:33

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 16:35:11

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 15:53:54

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 08:06:51

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

23 NOV 2020 10:57:44

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 08:09:27

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

04 DEC 2020 14:55:48

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 09:44:32

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

17 DEC 2020 10:09:48

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:07:19

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

31 DEC 2020 10:00:22

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 14:04:56

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

14 JAN 2021 14:08:19

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 13:14:11

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

28 JAN 2021 13:37:56

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

04 FEB 2021 13:37:43

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 13:29:50
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 FEB 2021 14:26:41
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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	25 FEB 2021 22:21:48
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

04 MAR 2021 14:15:37

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

11 MAR 2021 13:27:17

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

18 MAR 2021 14:11:33

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

25 MAR 2021 14:34:33

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

01 APR 2021 15:06:23

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 13:02:44

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 14:20:16

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 13:54:25

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 13:41:50

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐
Yes ☐

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Patient Cloud Open Date & Time	23 SEP 2021 00:01
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Patient Cloud Close Date & Time	27 SEP 2021 23:59
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US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2021 00:01
Patient Cloud Close Date & Time	25 OCT 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 495

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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°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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

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18 JUL 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐ Yes ☐

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3772041

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:48:08

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		04 MAR 2021 14:15:20

US3772041

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Mar 2021 00:25:03

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 02:52:59

Generated On: 10 Jun 2021 09:48:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 02:31:30

Generated On: 10 Jun 2021 09:48:08

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) _____

US3772041

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 02:52:59

Generated On: 10 Jun 2021 09:48:08

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.

US3772041

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 02:52:59

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 MAR 2021

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

17 MAR 2021 08:25

US3772041

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:52:59

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:41

Generated On: 10 Jun 2021 09:48:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3772041

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:41

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772041

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3772041

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:48:08

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"/>

US3772041

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:48:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3772041

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

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3772041

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 14 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3772041

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

10:05 (24 HR)

Collection date and time (derived)

14 JAN 2021 10:05

US3772041

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	10:03
Collection Date and Time (derived)	14 JAN 2021 10:03

US3772041

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 01:13:45

Generated On: 10 Jun 2021 09:48:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

AEID	USA-US107-2021-MRNA-1273-P30 1000011
Adverse event	EXACERBATION OF HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	15 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	16 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SUBJECT CALLED THE SITE
YESTERDAY 16FEB2021 AT
16:20 AND REPORTED THAT
SHE WENT TO THE ER WITH A
CHIEF COMPLAINT OF CHEST
PAIN. SHE WAS ADMITTED ON
15FEB2021. SHE REPORTED
BEING DISCHARGE AS HAVING
AN EXACERBATION OF HTN
AND WAS PRESCRIBED A NEW
HTN MED. RECORDS WERE
REQUESTED

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

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

AEID

Adverse event

HYPERLIPIDEMIA

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)

15 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 MAR 2021

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SUBJECT CALLED OUR SITE TO REPORT THEIR ADMISSION TO THE HOSPITAL ON 15-FEB-2021 DUE TO EXACERBATION OF THEIR HYPERTENSION WHICH WAS DOCUMENTED ON A SEPARATE SAE LOG. SUBJECT REPORTED HYPERLIPIDEMIA AS A SUB DIAGNOSIS DURING THEIR HOSPITAL VISIT. OUR SITE REQUESTED MEDICAL RECORDS. ON AN UNSCHEDULED CALL TO THE SUBJECT AFTER RECEIPT OF THEIR MEDICAL RECORDS ON 29MAR2021, SUBJECT REPORTED A RESOLUTION OF THEIR HYPERLIPIDEMIA ON 16MAR2021.

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)	

US3772041

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

AEID

Adverse event

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)

8 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 MAR 2021

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 ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SUBJECT CALLED THE SITE
TODAY REPORTING THAT
THEY WENT TO THE ER ON
MONDAY 08MAR2021 FEELING
HIGH HEARTBEAT AND
HAVING HIGHER BLOOD
PRESSURE. SUBJECT WAS NOT
ADMITTED TO THE HOSPITAL
AND WENT HOME , THEIR
DOCTOR INCREASED THE DOSE
OF THEIR LISINOPRIL AS A
RESULT.

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)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

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

Yes ☒

No ☐

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

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	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)		13 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)		13 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"/>

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
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"/>

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication EXACERBATION OF
HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	10 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication PREDNISOLONE SODIUM
PHOSPHATE 1%

Prophylaxis Yes ☐
No ☒

Indication CORNEA TRANSPLANT . RIGHT
EYE.

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

Name of Medication TIMOLOL MALEATE 0.5%

Prophylaxis Yes ☐
No ☒

Indication GLAUCOMA RIGHT EYE

Dose per administration 1

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

If dose unit is Other, specify DROP

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
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"/>

US3772041

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Mar 2021 02:52:58

Generated On: 10 Jun 2021 09:48:08

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3772041

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:48:08

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

US3772041

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:48:08

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 ☐

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SAEID	USA-US107-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SAEID	USA-US107-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	18/FEB/2021 09:46
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

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 19:45:23

Generated On: 10 Jun 2021 09:48:08

SAEID	USA-US107-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	06/APR/2021 13:41
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

US3772041 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

US3772041

Form: Participant Creation

Generated On: 10 Jun 2021 09:48:08

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'US3772041'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 16:45:06

US3772041

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:13:08

US3772041

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:45:07

US3772041

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:13:08

US3772041

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'SCRN'	System	11 Aug 2020 17:13:08

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered (b) (6) 1933'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:45:08

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '87'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'YEARS'	System	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '87'	System	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:48:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:19

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Aug 2020'	System	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '2020'	System	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	19 Aug 2020 20:49:39
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:45

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 16:45:07

US3772041

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:48:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'I'	System	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:48:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:15:02

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
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.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:15
Data point term sent to Coder	System	11 Aug 2020 17:16:03
User entered 'Hypertension'	(b) (4), (b) (6)	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 2017' reason for change:	(b) (4)	06 Oct 2020 23:14:49
Data Entry Error	Emily Crews (b) (4)	
User entered '11 Aug 2020'	(b) (4)	11 Aug 2020 17:15:37
	(b) (4), (b) (6)	

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 2017'	System	06 Oct 2020 23:14:49
User entered 'Aug 2020'	System	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '2017'	System	06 Oct 2020 23:14:49
User entered '2020'	System	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered empty.	System	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered empty.	System	11 Aug 2020 17:15:37

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Aug 2020 17:18:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:18:22
Data point term sent to Coder	System	11 Aug 2020 17:17:03
User entered 'Thyroidectomy'	(b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 2015'	System	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '2015'	System	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 2015'	System	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '2015'	System	11 Aug 2020 17:16:18

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User closed query 'Please confirm if complete or partial hysterectomy.' (Site from CRA).	(b) (4)	21 Feb 2021 04:55:46
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	08 Dec 2020 22:39:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	08 Dec 2020 22:39:50
Data point term sent to Coder	System	08 Dec 2020 22:38:36
Query 'Please confirm if complete or partial hysterectomy.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 22:38:21
Coding entries removed.	(b) (4), (b) (6)	08 Dec 2020 22:38:11
User entered 'COMPLETE HYSTERECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Dec 2020 22:38:11
User opened query 'Please confirm if complete or partial hysterectomy.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:24:35
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)	06 Oct 2020 23:14:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Oct 2020 23:14:23
Data point term sent to Coder	System	06 Oct 2020 23:13:18
User entered 'Hysterectomy'	Emily Crews (b) (4)	06 Oct 2020 23:13:15
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 1995'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 1995'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 1995'	System	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '1995'	System	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 1995'	System	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '1995'	System	06 Oct 2020 23:13:15

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 23:15:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 23:15:24
Data point term sent to Coder	System	06 Oct 2020 23:14:21
User entered 'Hypothyroidism'	Emily Crews (b) (4)	06 Oct 2020 23:13:40
	(b) (4)	

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 2015'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'Jan 2015'	System	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '2015'	System	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered empty.	System	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:31:35
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered empty.	System	06 Oct 2020 23:13:40

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	02 May 2021 08:43:29
Data hard locked.		01 May 2021 20:19:50
Data hard unlocked.		29 Apr 2021 13:31:35
Data hard locked.		27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '09:46'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '11 Aug 2020 09:46'	System	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '149' cm	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51
DataPoint set to visible.	System	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '49.5' kg	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51
DataPoint set to visible.	System	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Amendment Manager: User entered '22.29629'	System	16 Sep 2020 23:51:51
User entered '22.3'	System	11 Aug 2020 17:17:51
DataPoint set to visible.	System	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'kg/m2'	System	11 Aug 2020 17:17:51
DataPoint set to visible.	System	11 Aug 2020 17:14:52

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User closed query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:37:09
Query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' answered with 'Updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:27
User opened query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:28:36
User entered '36.2' C	(b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty; reason for change Data Entry Error	(b) (4) Emily Crews (b) (4)	15 Sep 2020 23:15:27
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:27
User entered '68'	(b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'bpm'	System	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:27
User entered '18'	(b) (4), (b) (6)	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'breaths/min'	System	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:27
User entered '138'	Emily Crews (b) (4)	11 Aug 2020 17:17:51
	(b) (4), (b) (6)	

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'mmHg'	System	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:27
User entered '88'	Emily Crews (b) (4)	11 Aug 2020 17:17:51
	(b) (4), (b) (6)	

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered 'mmHg'	System	11 Aug 2020 17:17:51

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:28:14

US3772041

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:26

US3772041

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:59:04
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 20:45:57
User entered '11 Aug 2020'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:26

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '11 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) Emily Crews (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
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)	12 Oct 2020 14:08:58
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 'this has been updated' (Site from DM).	Emily Crews (b) (4)	07 Oct 2020 15:44:48
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)	05 Oct 2020 07:50:17
User entered 'Surgically sterile (SURGICALLY STERILE)'	Emily Crews (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'un UNK 1995'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:48:08

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:29:44

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:48:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:34

US3772041

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:52

US3772041

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:52

US3772041

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 17:18:52

US3772041

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'VISIT1'	System	11 Aug 2020 17:18:52

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:59:45

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:35:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:35:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 17:59:45
User entered '185699' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:59:45

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 17:59:45

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	Emily Crews (b) (4)	11 Aug 2020 18:30:02

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	Emily Crews (b) (4)	11 Aug 2020 18:30:02

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:02

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:02

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:02

US3772041

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:48:08

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User closed query 'Please confirm if subject have HIV infection.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 22:55:32
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
Query 'Please confirm if subject have HIV infection.' answered with 'updated' (Site from CRA).	(b) (4)	04 Dec 2020 21:54:32
User entered 'No (N)'	Emily Crews (b) (4)	04 Dec 2020 21:54:27
User opened query 'Please confirm if subject have HIV infection.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:25:41
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:31:58

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:58:12
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:48
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:29:04
User entered '149' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:48
User entered '49.5' kg	Emily Crews (b) (4)	11 Aug 2020 19:14:09
	(b) (4)	

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:58:12
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:48
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:29:04
User entered '149' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:48
User entered '49.5' kg	Emily Crews (b) (4)	11 Aug 2020 19:14:09
	(b) (4)	

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '09:46'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '11 Aug 2020 09:46'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '36.2' C	(b) (4) Emily Crews (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '68'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'bpm'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'breaths/min'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '138'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '88'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:58:12
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'ND' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 23:15:48
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:29:04
User entered '149' cm	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:48:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 23:15:48
User entered '49.5' kg	Emily Crews (b) (4)	11 Aug 2020 19:14:09
	(b) (4)	

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 13:36:38
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 19:14:09
User entered '12:00'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '36.1' C	(b) (4) Emily Crews (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '66'	Emily Crews (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'bpm'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'breaths/min'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '108'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '60'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	11 Aug 2020 19:14:09

US3772041

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:33

US3772041

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	Emily Crews (b) (4)	11 Aug 2020 18:30:33

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	Emily Crews (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11:23'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '11 Aug 2020 11:23'	System	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Left Arm (LEFT ARM)'	Emily Crews (b) (4)	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'ONCE'	System	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 18:30:58

US3772041

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	11 Aug 2020 18:31:47

US3772041

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:47

US3772041

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11:05'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:47

US3772041

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '11 Aug 2020 11:05'	System	11 Aug 2020 18:31:47

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11 Aug 2020'	Emily Crews (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11:07'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '11 Aug 2020 11:07'	System	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered empty.	System	11 Aug 2020 18:31:59

US3772041

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:32:05

US3772041

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '1'	System	11 Aug 2020 18:32:05

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:02:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '1b6416a4-1379-4836-a949-103814f52c78' User entered 'Yes (Y)'	System	11 Aug 2020 19:03:33
	System	11 Aug 2020 19:03:33

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:02:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '1b6416a4-1379-4836-a949-103814f52c78' User entered '96.9'	System	11 Aug 2020 19:03:33
	System	11 Aug 2020 19:03:33

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:03:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '1b6416a4-1379-4836-a949-103814f52c78'	System	11 Aug 2020 19:03:33
User entered 'No (N)'	System	11 Aug 2020 19:03:33

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:03:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '1b6416a4-1379-4836-a949-103814f52c78' User entered '11 Aug 2020 12:03'	System	11 Aug 2020 19:03:33
	System	11 Aug 2020 19:03:33

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 11:43'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 14:13'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:18:39', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '19f600af-c187-418b-82c8-0ecc6b4f22a0' User entered 'Yes (Y)'	System	12 Aug 2020 13:19:25
	System	12 Aug 2020 13:19:25

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '19f600af-c187-418b-82c8-0ecc6b4f22a0' User entered '97.6'	System	12 Aug 2020 13:19:25
	System	12 Aug 2020 13:19:25

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:08', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '19f600af-c187-418b-82c8-0ecc6b4f22a0' User entered 'No (N)'	System	12 Aug 2020 13:19:25
	System	12 Aug 2020 13:19:25

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:20', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '19f600af-c187-418b-82c8-0ecc6b4f22a0' User entered '12 Aug 2020 06:19'	System	12 Aug 2020 13:19:25
	System	12 Aug 2020 13:19:25

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 15:08'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 2'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:57:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cb9c7d33-7b93-464a-b3c8-2fc08b0bae4e' User entered 'Yes (Y)'	System	13 Aug 2020 13:58:26
	System	13 Aug 2020 13:58:26

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cb9c7d33-7b93-464a-b3c8-2fc08b0bae4e' User entered '98.2'	System	13 Aug 2020 13:58:26
	System	13 Aug 2020 13:58:26

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cb9c7d33-7b93-464a-b3c8-2fc08b0bae4e' User entered 'No (N)'	System	13 Aug 2020 13:58:26
	System	13 Aug 2020 13:58:26

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:23', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cb9c7d33-7b93-464a-b3c8-2fc08b0bae4e' User entered '13 Aug 2020 06:58'	System	13 Aug 2020 13:58:26
	System	13 Aug 2020 13:58:26

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 3'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:02:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd44c616a-47d2-4092-9cec-e96b2207f296' User entered 'Yes (Y)'	System	14 Aug 2020 13:03:11
	System	14 Aug 2020 13:03:11

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:02:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd44c616a-47d2-4092-9cec-e96b2207f296' User entered '97.6'	System	14 Aug 2020 13:03:11
	System	14 Aug 2020 13:03:11

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:02:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd44c616a-47d2-4092-9cec-e96b2207f296'	System	14 Aug 2020 13:03:11
User entered 'No (N)'	System	14 Aug 2020 13:03:11

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:07', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd44c616a-47d2-4092-9cec-e96b2207f296' User entered '14 Aug 2020 06:03'	System	14 Aug 2020 13:03:11
	System	14 Aug 2020 13:03:11

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 4'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:32:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa8e8888-f6bb-4d7e-b92e-340c8974116f' User entered 'Yes (Y)'	System	15 Aug 2020 12:33:12
	System	15 Aug 2020 12:33:12

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:32:55', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa8e8888-f6bb-4d7e-b92e-340c8974116f' User entered '98.0'	System	15 Aug 2020 12:33:12
	System	15 Aug 2020 12:33:12

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa8e8888-f6bb-4d7e-b92e-340c8974116f' User entered 'No (N)'	System	15 Aug 2020 12:33:12
	System	15 Aug 2020 12:33:12

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa8e8888-f6bb-4d7e-b92e-340c8974116f' User entered '15 Aug 2020 05:33'	System	15 Aug 2020 12:33:12
	System	15 Aug 2020 12:33:12

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 5'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T06:08:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ecfa405e-0b85-473e-bcad-43939571113b' User entered 'Yes (Y)'	System	16 Aug 2020 14:19:09
	System	16 Aug 2020 14:19:09

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:18:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ecfa405e-0b85-473e-bcad-43939571113b' User entered '98.0'	System	16 Aug 2020 14:19:09
	System	16 Aug 2020 14:19:09

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:18:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ecfa405e-0b85-473e-bcad-43939571113b' User entered 'No (N)'	System	16 Aug 2020 14:19:09
	System	16 Aug 2020 14:19:09

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:07', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ecfa405e-0b85-473e-bcad-43939571113b' User entered '16 Aug 2020 07:19'	System	16 Aug 2020 14:19:09
	System	16 Aug 2020 14:19:09

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 6'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:17:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '5c42558c-5f51-419d-bb14-d2ac542766ce' User entered 'Yes (Y)'	System	08 Sep 2020 19:44:39
	System	08 Sep 2020 19:44:39

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:38:39', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '5c42558c-5f51-419d-bb14-d2ac542766ce' User entered '98.0'	System	08 Sep 2020 19:44:39
	System	08 Sep 2020 19:44:39

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:38:45', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '5c42558c-5f51-419d-bb14-d2ac542766ce' User entered 'No (N)'	System	08 Sep 2020 19:44:39
	System	08 Sep 2020 19:44:39

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:38:52', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '5c42558c-5f51-419d-bb14-d2ac542766ce' User entered '17 Aug 2020 06:38'	System	08 Sep 2020 19:44:39
	System	08 Sep 2020 19:44:39

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 7'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:04:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b2ef75cf-32ae-4ac0-91e7-69f89d20ce8c'	System	11 Aug 2020 19:04:50
User entered 'None (1)'	System	11 Aug 2020 19:04:50

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:04:25', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b2ef75cf-32ae-4ac0-91e7-69f89d20ce8c'	System	11 Aug 2020 19:04:50
User entered 'No (N)'	System	11 Aug 2020 19:04:50

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:04:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b2ef75cf-32ae-4ac0-91e7-69f89d20ce8c'	System	11 Aug 2020 19:04:50
User entered 'No (N)'	System	11 Aug 2020 19:04:50

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:04:40', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b2ef75cf-32ae-4ac0-91e7-69f89d20ce8c' User entered 'None (1)'	System	11 Aug 2020 19:04:50
	System	11 Aug 2020 19:04:50

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:04:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b2ef75cf-32ae-4ac0-91e7-69f89d20ce8c' User entered '11 Aug 2020 12:04'	System	11 Aug 2020 19:04:50
	System	11 Aug 2020 19:04:50

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 11:43'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 14:13'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4749489-753e-4c73-8a7a-3edd136e300c' User entered 'None (1)'	System	12 Aug 2020 13:20:11
	System	12 Aug 2020 13:20:11

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4749489-753e-4c73-8a7a-3edd136e300c' User entered 'No (N)'	System	12 Aug 2020 13:20:11
	System	12 Aug 2020 13:20:11

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4749489-753e-4c73-8a7a-3edd136e300c' User entered 'No (N)'	System	12 Aug 2020 13:20:11
	System	12 Aug 2020 13:20:11

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:19:54', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4749489-753e-4c73-8a7a-3edd136e300c'	System	12 Aug 2020 13:20:11
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 13:20:11

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-12T06:20:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4749489-753e-4c73-8a7a-3edd136e300c' User entered '12 Aug 2020 06:20'	System	12 Aug 2020 13:20:11
	System	12 Aug 2020 13:20:11

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 15:08'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 2'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73797fce-5f52-4733-b18a-83150f6dceda'	System	13 Aug 2020 13:59:16
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 13:59:16

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:42', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73797fce-5f52-4733-b18a-83150f6dceda'	System	13 Aug 2020 13:59:16
User entered 'No (N)'	System	13 Aug 2020 13:59:16

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73797fce-5f52-4733-b18a-83150f6dceda' User entered 'No (N)'	System	13 Aug 2020 13:59:16
	System	13 Aug 2020 13:59:16

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:58:57', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73797fce-5f52-4733-b18a-83150f6dceda' User entered 'None (1)'	System	13 Aug 2020 13:59:16
	System	13 Aug 2020 13:59:16

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-13T06:59:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73797fce-5f52-4733-b18a-83150f6dceda' User entered '13 Aug 2020 06:59'	System	13 Aug 2020 13:59:16
	System	13 Aug 2020 13:59:16

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 3'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '9dbe7302-fcfd-496c-8a56-45b9fede60b2'	System	14 Aug 2020 13:03:51
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 13:03:51

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '9dbe7302-fcfd-496c-8a56-45b9fede60b2'	System	14 Aug 2020 13:03:51
User entered 'No (N)'	System	14 Aug 2020 13:03:51

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '9dbe7302-fcfd-496c-8a56-45b9fede60b2'	System	14 Aug 2020 13:03:51
User entered 'No (N)'	System	14 Aug 2020 13:03:51

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '9dbe7302-fcfd-496c-8a56-45b9fede60b2'	System	14 Aug 2020 13:03:51
User entered 'None (1)'	System	14 Aug 2020 13:03:51

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:03:49', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '9dbe7302-fcfd-496c-8a56-45b9fede60b2' User entered '14 Aug 2020 06:03'	System	14 Aug 2020 13:03:51
	System	14 Aug 2020 13:03:51

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 4'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:23', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '16a39e0e-f7d7-4d90-84ed-e58dd5b68dbf' User entered 'None (1)'	System	15 Aug 2020 12:33:49
	System	15 Aug 2020 12:33:49

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '16a39e0e-f7d7-4d90-84ed-e58dd5b68dbf' User entered 'No (N)'	System	15 Aug 2020 12:33:49
	System	15 Aug 2020 12:33:49

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '16a39e0e-f7d7-4d90-84ed-e58dd5b68dbf' User entered 'No (N)'	System	15 Aug 2020 12:33:49
	System	15 Aug 2020 12:33:49

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '16a39e0e-f7d7-4d90-84ed-e58dd5b68dbf' User entered 'None (1)'	System	15 Aug 2020 12:33:49
	System	15 Aug 2020 12:33:49

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '16a39e0e-f7d7-4d90-84ed-e58dd5b68dbf' User entered '15 Aug 2020 05:33'	System	15 Aug 2020 12:33:49
	System	15 Aug 2020 12:33:49

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 5'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:19', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '17121693-7f75-4fd0-a235-f8005d5a3daa'	System	16 Aug 2020 14:19:41
User entered 'None (1)'	System	16 Aug 2020 14:19:41

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:25', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '17121693-7f75-4fd0-a235-f8005d5a3daa'	System	16 Aug 2020 14:19:41
User entered 'No (N)'	System	16 Aug 2020 14:19:41

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:28', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '17121693-7f75-4fd0-a235-f8005d5a3daa'	System	16 Aug 2020 14:19:41
User entered 'No (N)'	System	16 Aug 2020 14:19:41

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '17121693-7f75-4fd0-a235-f8005d5a3daa'	System	16 Aug 2020 14:19:41
User entered 'None (1)'	System	16 Aug 2020 14:19:41

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:37', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '17121693-7f75-4fd0-a235-f8005d5a3daa' User entered '16 Aug 2020 07:19'	System	16 Aug 2020 14:19:41
	System	16 Aug 2020 14:19:41

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 6'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:04', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '0798c4b0-32ce-4d42-8cf8-8daa75709b6f' User entered 'None (1)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '0798c4b0-32ce-4d42-8cf8-8daa75709b6f' User entered 'No (N)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:13', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '0798c4b0-32ce-4d42-8cf8-8daa75709b6f' User entered 'No (N)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:18', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '0798c4b0-32ce-4d42-8cf8-8daa75709b6f' User entered 'None (1)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '0798c4b0-32ce-4d42-8cf8-8daa75709b6f' User entered '17 Aug 2020 06:39'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 7'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:17', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:26', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:35', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'None (0)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:40', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered 'No (N)'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-11T12:05:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e5c36044-878f-43ca-8b9d-2e27716660cc' User entered '11 Aug 2020 12:05'	System	11 Aug 2020 19:05:50
	System	11 Aug 2020 19:05:50

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 11:43'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 14:13'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Aug 2020 15:08'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 2'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 3'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:05', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:13', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:17', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:24', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered 'None (0)'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881'	System	14 Aug 2020 13:04:38
User entered 'No (N)'	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-14T06:04:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '50293654-80d1-4c12-bb5a-c17475b56881' User entered '14 Aug 2020 06:04'	System	14 Aug 2020 13:04:38
	System	14 Aug 2020 13:04:38

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 4'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:51', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:33:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:04', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:08', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered 'None (0)'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:20', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3'	System	15 Aug 2020 12:34:31
User entered 'No (N)'	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-15T05:34:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b24ef56b-0cc6-4956-892a-487584704fd3' User entered '15 Aug 2020 05:34'	System	15 Aug 2020 12:34:31
	System	15 Aug 2020 12:34:31

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 5'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:45', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'None (0)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'None (0)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32'	System	16 Aug 2020 14:20:16
User entered 'No interference with activity (1)'	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:19:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'None (0)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:20:03', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'None (0)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:20:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'None (0)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:20:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered 'No (N)'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-16T07:20:13', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '8cd22dbd-5a66-4941-a901-0dd674edaf32' User entered '16 Aug 2020 07:20'	System	16 Aug 2020 14:20:16
	System	16 Aug 2020 14:20:16

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 6'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered 'None (0)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:37', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e'	System	08 Sep 2020 19:44:40
User entered 'No interference with activity (1)'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e'	System	08 Sep 2020 19:44:40
User entered 'No interference with activity (1)'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered 'None (0)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:49', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered 'None (0)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:51', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered 'None (0)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:39:55', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered 'No (N)'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-08-17T06:40:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd7738e8d-dff5-4a33-b5bd-98ce0305879e' User entered '17 Aug 2020 06:40'	System	08 Sep 2020 19:44:40
	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 7'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:44:40
User entered 'Day 8'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 12:00'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '19 Aug 2020 11:59'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:44:40
User entered 'Day 8'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 12:00'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '19 Aug 2020 11:59'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:44:40
User entered 'Day 8'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '18 Aug 2020 12:00'	System	08 Sep 2020 19:44:40

US3772041

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '19 Aug 2020 11:59'	System	08 Sep 2020 19:44:40

US3772041

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:41:03

US3772041

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:41:03

US3772041

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:41:03

US3772041

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:41:03

US3772041

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 15:41:12

US3772041

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	18 Aug 2020 15:41:12

US3772041

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	25 Aug 2020 19:53:58

US3772041

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '25 Aug 2020'	Sarah Sandberg (b) (4)	25 Aug 2020 19:53:58

US3772041

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	25 Aug 2020 19:53:58

US3772041

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	25 Aug 2020 19:53:58
	(b) (4)	

US3772041

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	25 Aug 2020 19:54:03

US3772041

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	25 Aug 2020 19:54:03

US3772041

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Sep 2020 23:37:37

US3772041

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '1 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Sep 2020 23:37:37

US3772041

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Sep 2020 23:37:37

US3772041

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Sep 2020 23:37:37

US3772041

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Sep 2020 23:37:41

US3772041

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	01 Sep 2020 23:37:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:45:57

US3772041

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:45:57

US3772041

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:45:57

US3772041

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'VISIT2'	System	08 Sep 2020 20:45:57

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '10:40'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '08 Sep 2020 10:40'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '36.5' C	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '64'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'bpm'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '16'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'breaths/min'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '125'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '70'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '12:43'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '08 Sep 2020 12:43'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '36.5' C	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '53'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'bpm'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '18'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'breaths/min'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '155'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '74'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	08 Sep 2020 20:48:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:12

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '08 Sep 2020'	(b) (4) Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '12:00'	Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Left Arm (LEFT ARM)'	Matthew Pohlmeier (b) (4)	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'ONCE'	System	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:48:08

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 19:35:55

US3772041

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	08 Sep 2020 20:46:30

US3772041

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:30

US3772041

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11:16'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:30

US3772041

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '08 Sep 2020 11:16'	System	08 Sep 2020 20:46:30

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '11:18'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '08 Sep 2020 11:18'	System	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered empty.	System	08 Sep 2020 20:46:41

US3772041

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	08 Sep 2020 20:48:29

US3772041

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	08 Sep 2020 20:48:29

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '52b69161-97ec-493d-bb61-ff4822d3666d' User entered 'Yes (Y)'	System	08 Sep 2020 19:45:35
	System	08 Sep 2020 19:45:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:24', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '52b69161-97ec-493d-bb61-ff4822d3666d' User entered '97.7'	System	08 Sep 2020 19:45:35
	System	08 Sep 2020 19:45:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '52b69161-97ec-493d-bb61-ff4822d3666d' User entered 'No (N)'	System	08 Sep 2020 19:45:35
	System	08 Sep 2020 19:45:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:32', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '52b69161-97ec-493d-bb61-ff4822d3666d' User entered '08 Sep 2020 12:45'	System	08 Sep 2020 19:45:35
	System	08 Sep 2020 19:45:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 12:20'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:03:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b58d56ac-479f-454b-bda0-902fd76e627f' User entered 'Yes (Y)'	System	10 Sep 2020 16:30:45
	System	10 Sep 2020 16:30:45

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:03:55', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b58d56ac-479f-454b-bda0-902fd76e627f' User entered '98.1'	System	10 Sep 2020 16:30:45
	System	10 Sep 2020 16:30:45

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b58d56ac-479f-454b-bda0-902fd76e627f' User entered 'No (N)'	System	10 Sep 2020 16:30:45
	System	10 Sep 2020 16:30:45

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b58d56ac-479f-454b-bda0-902fd76e627f' User entered '08 Sep 2020 18:04'	System	10 Sep 2020 16:30:45
	System	10 Sep 2020 16:30:45

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 15:45'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 2'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:13:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e149121d-2338-4948-8894-50ef4738b68d' User entered 'Yes (Y)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:14:02', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e149121d-2338-4948-8894-50ef4738b68d' User entered '98.8'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:14:07', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e149121d-2338-4948-8894-50ef4738b68d' User entered 'No (N)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:14:17', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e149121d-2338-4948-8894-50ef4738b68d' User entered '09 Sep 2020 18:14'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 3'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:02', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7256f27a-b219-4e80-bcf2-4c42062ad354' User entered 'Yes (Y)'	System	11 Sep 2020 01:10:35
	System	11 Sep 2020 01:10:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:18', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7256f27a-b219-4e80-bcf2-4c42062ad354' User entered '98.2'	System	11 Sep 2020 01:10:35
	System	11 Sep 2020 01:10:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7256f27a-b219-4e80-bcf2-4c42062ad354'	System	11 Sep 2020 01:10:35
User entered 'No (N)'	System	11 Sep 2020 01:10:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:32', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7256f27a-b219-4e80-bcf2-4c42062ad354' User entered '10 Sep 2020 18:10'	System	11 Sep 2020 01:10:35
	System	11 Sep 2020 01:10:35

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 4'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:35:20', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd085bb97-f022-44d6-bf70-58f0bbb270c1' User entered 'Yes (Y)'	System	12 Sep 2020 01:37:22
	System	12 Sep 2020 01:37:22

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd085bb97-f022-44d6-bf70-58f0bbb270c1' User entered '98.1'	System	12 Sep 2020 01:37:22
	System	12 Sep 2020 01:37:22

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd085bb97-f022-44d6-bf70-58f0bbb270c1' User entered 'No (N)'	System	12 Sep 2020 01:37:22
	System	12 Sep 2020 01:37:22

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:18', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd085bb97-f022-44d6-bf70-58f0bbb270c1' User entered '11 Sep 2020 18:37'	System	12 Sep 2020 01:37:22
	System	12 Sep 2020 01:37:22

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 5'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:28:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '050d4779-e190-4123-9574-fe928690d4ee' User entered 'Yes (Y)'	System	13 Sep 2020 01:29:17
	System	13 Sep 2020 01:29:17

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:28:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '050d4779-e190-4123-9574-fe928690d4ee' User entered '98.2'	System	13 Sep 2020 01:29:17
	System	13 Sep 2020 01:29:17

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:29:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '050d4779-e190-4123-9574-fe928690d4ee' User entered 'No (N)'	System	13 Sep 2020 01:29:17
	System	13 Sep 2020 01:29:17

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:29:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '050d4779-e190-4123-9574-fe928690d4ee' User entered '12 Sep 2020 18:29'	System	13 Sep 2020 01:29:17
	System	13 Sep 2020 01:29:17

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 6'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:08', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f5da3e01-affb-41df-a9cc-34008d80a8f9' User entered 'Yes (Y)'	System	14 Sep 2020 01:40:32
	System	14 Sep 2020 01:40:32

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f5da3e01-affb-41df-a9cc-34008d80a8f9' User entered '98.1'	System	14 Sep 2020 01:40:32
	System	14 Sep 2020 01:40:32

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f5da3e01-affb-41df-a9cc-34008d80a8f9'	System	14 Sep 2020 01:40:32
User entered 'No (N)'	System	14 Sep 2020 01:40:32

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f5da3e01-affb-41df-a9cc-34008d80a8f9' User entered '13 Sep 2020 18:40'	System	14 Sep 2020 01:40:32
	System	14 Sep 2020 01:40:32

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 7'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:11:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '59da299b-4921-4933-a855-f78f8aee4009' User entered 'Yes (Y)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:11:55', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '59da299b-4921-4933-a855-f78f8aee4009' User entered '98.0'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '59da299b-4921-4933-a855-f78f8aee4009'	System	15 Sep 2020 01:12:12
User entered 'No (N)'	System	15 Sep 2020 01:12:12

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:08', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '59da299b-4921-4933-a855-f78f8aee4009' User entered '14 Sep 2020 18:12'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '25effb9c-7e2e-4110-9173-348869118175' User entered 'None (1)'	System	08 Sep 2020 19:46:11
	System	08 Sep 2020 19:46:11

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:45:53', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '25effb9c-7e2e-4110-9173-348869118175' User entered 'No (N)'	System	08 Sep 2020 19:46:11
	System	08 Sep 2020 19:46:11

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '25effb9c-7e2e-4110-9173-348869118175' User entered 'No (N)'	System	08 Sep 2020 19:46:11
	System	08 Sep 2020 19:46:11

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '25effb9c-7e2e-4110-9173-348869118175' User entered 'None (1)'	System	08 Sep 2020 19:46:11
	System	08 Sep 2020 19:46:11

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '25effb9c-7e2e-4110-9173-348869118175' User entered '08 Sep 2020 12:46'	System	08 Sep 2020 19:46:11
	System	08 Sep 2020 19:46:11

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 12:20'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:28', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd3a80e92-4752-4484-b398-413bbde2c56d' User entered 'None (1)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:32', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd3a80e92-4752-4484-b398-413bbde2c56d' User entered 'No (N)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:35', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd3a80e92-4752-4484-b398-413bbde2c56d' User entered 'No (N)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:40', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd3a80e92-4752-4484-b398-413bbde2c56d' User entered 'None (1)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:47', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd3a80e92-4752-4484-b398-413bbde2c56d' User entered '08 Sep 2020 18:04'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 15:45'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 2'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:14:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066'	System	10 Sep 2020 16:30:48
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:14:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066' User entered 'No (N)'	System	10 Sep 2020 16:30:48
	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:15:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066'	System	10 Sep 2020 16:30:48
User entered 'Yes (Y)'	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:15:54', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066' User entered '5'	System	10 Sep 2020 16:30:48
	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:16:10', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066'	System	10 Sep 2020 16:30:48
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-09T18:16:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '430f6fcd-1a4d-4d52-bd3c-55f70ad04066'	System	10 Sep 2020 16:30:48
User entered '09 Sep 2020 18:16'	System	10 Sep 2020 16:30:48

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 3'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b'	System	11 Sep 2020 01:11:58
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:10:51', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered 'Yes (Y)'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:11:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered '3'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:11:28', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered 'Yes (Y)'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:11:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered '4'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:11:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered 'None (1)'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:11:55', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4cf1575e-bef2-4b10-8dfe-1153892c484b' User entered '10 Sep 2020 18:11'	System	11 Sep 2020 01:11:58
	System	11 Sep 2020 01:11:58

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 4'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a'	System	12 Sep 2020 01:38:03
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a' User entered 'No (N)'	System	12 Sep 2020 01:38:03
	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a' User entered 'Yes (Y)'	System	12 Sep 2020 01:38:03
	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a' User entered '3'	System	12 Sep 2020 01:38:03
	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:37:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a' User entered 'None (1)'	System	12 Sep 2020 01:38:03
	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '73db4845-6d6e-41d9-8628-5c90ece3a86a' User entered '11 Sep 2020 18:38'	System	12 Sep 2020 01:38:03
	System	12 Sep 2020 01:38:03

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 5'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:29:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7'	System	13 Sep 2020 01:30:23
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:29:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7' User entered 'No (N)'	System	13 Sep 2020 01:30:23
	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:29:42', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7' User entered 'Yes (Y)'	System	13 Sep 2020 01:30:23
	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7' User entered '2'	System	13 Sep 2020 01:30:23
	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7' User entered 'None (1)'	System	13 Sep 2020 01:30:23
	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:21', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c7998b2b-fa78-4bcc-90f0-1dee317469a7' User entered '12 Sep 2020 18:30'	System	13 Sep 2020 01:30:23
	System	13 Sep 2020 01:30:23

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 6'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675'	System	14 Sep 2020 01:41:38
User entered 'None (1)'	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675'	System	14 Sep 2020 01:41:38
User entered 'No (N)'	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:40:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675'	System	14 Sep 2020 01:41:38
User entered 'Yes (Y)'	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675' User entered '1'	System	14 Sep 2020 01:41:38
	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:19', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675'	System	14 Sep 2020 01:41:38
User entered 'None (1)'	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '4c222d6f-f3bf-44d9-be73-6376a2626675' User entered '13 Sep 2020 18:41'	System	14 Sep 2020 01:41:38
	System	14 Sep 2020 01:41:38

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 7'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e2c88571-d616-4493-8041-cdc24f7000c4'	System	15 Sep 2020 01:12:47
User entered 'None (1)'	System	15 Sep 2020 01:12:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:26', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e2c88571-d616-4493-8041-cdc24f7000c4' User entered 'No (N)'	System	15 Sep 2020 01:12:47
	System	15 Sep 2020 01:12:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e2c88571-d616-4493-8041-cdc24f7000c4' User entered 'No (N)'	System	15 Sep 2020 01:12:47
	System	15 Sep 2020 01:12:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e2c88571-d616-4493-8041-cdc24f7000c4'	System	15 Sep 2020 01:12:47
User entered 'None (1)'	System	15 Sep 2020 01:12:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'e2c88571-d616-4493-8041-cdc24f7000c4' User entered '14 Sep 2020 18:12'	System	15 Sep 2020 01:12:47
	System	15 Sep 2020 01:12:47

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:20', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:24', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:28', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:35', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'None (0)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered 'No (N)'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T12:46:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a419dc83-8e64-4384-949f-e6ba50cbfdde' User entered '08 Sep 2020 12:46'	System	08 Sep 2020 19:46:47
	System	08 Sep 2020 19:46:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 12:20'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 14:50'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:04:58', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:01', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:17', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'None (0)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:23', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered 'No (N)'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-08T18:05:49', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7b4745e2-84d6-47ec-9c37-5fbf069239d5' User entered '08 Sep 2020 18:05'	System	10 Sep 2020 16:30:47
	System	10 Sep 2020 16:30:47

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '08 Sep 2020 15:45'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 2'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 3'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:12:31', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'None (0)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:12:39', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'Some interference with activity (2)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:12:51', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'None (0)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:12:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'None (0)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:13:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'None (0)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:13:05', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'None (0)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:13:12', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered 'No (N)'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-10T18:13:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'f1135b3b-fe32-469a-bf94-8e379383d73b' User entered '10 Sep 2020 18:13'	System	11 Sep 2020 01:13:33
	System	11 Sep 2020 01:13:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 4'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:21', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:25', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:32', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:35', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'None (0)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered 'No (N)'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-11T18:38:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'c4d0d456-1606-435e-84ce-8adcc3c51f7f' User entered '11 Sep 2020 18:38'	System	12 Sep 2020 01:38:48
	System	12 Sep 2020 01:38:48

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 5'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:34', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:42', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:45', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872' User entered 'None (0)'	System	13 Sep 2020 01:31:01
	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:53', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872'	System	13 Sep 2020 01:31:01
User entered 'No (N)'	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-12T18:30:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '40810034-cc6e-4923-a385-3eba17a56872'	System	13 Sep 2020 01:31:01
User entered '12 Sep 2020 18:30'	System	13 Sep 2020 01:31:01

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 6'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:41:52', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:42:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:42:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:42:16', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered 'None (0)'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:42:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445'	System	14 Sep 2020 01:42:33
User entered 'No (N)'	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-13T18:42:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '2855dbf4-414f-407e-807b-70f675799445' User entered '13 Sep 2020 18:42'	System	14 Sep 2020 01:42:33
	System	14 Sep 2020 01:42:33

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	08 Sep 2020 19:35:55
User entered 'Day 7'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:52', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:12:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:13:02', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:13:06', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:13:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'None (0)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:13:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered 'No (N)'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-09-14T18:13:19', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '655b6e07-8b4d-49de-a4e6-fff7d4d71dd9' User entered '14 Sep 2020 18:13'	System	15 Sep 2020 01:13:22
	System	15 Sep 2020 01:13:22

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:35:55

US3772041

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:48:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:35:55

US3772041

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	15 Sep 2020 23:46:39

US3772041

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '15 Sep 2020'	Sarah Sandberg (b) (4)	15 Sep 2020 23:46:39

US3772041

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4)	15 Sep 2020 23:46:39

US3772041

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	Sarah Sandberg (b) (4)	15 Sep 2020 23:46:39

US3772041

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	15 Sep 2020 23:46:42

US3772041

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	15 Sep 2020 23:46:42

US3772041

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	22 Sep 2020 16:34:30

US3772041

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '22 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 16:34:30

US3772041

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4)	22 Sep 2020 16:34:30

US3772041

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 16:34:30

US3772041

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	22 Sep 2020 16:34:36

US3772041

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	22 Sep 2020 16:34:36

US3772041

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:26:48

US3772041

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered '29 Sep 2020'	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:26:48

US3772041

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:26:48

US3772041

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:26:48

US3772041

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:01
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	13 Oct 2020 15:26:56

US3772041

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	13 Oct 2020 15:26:56

US3772041

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	13 Oct 2020 15:27:14

US3772041

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '13 Oct 2020'	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:27:14

US3772041

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[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 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Clinic (Clinic)'	Matthew Pohlmeier (b) (4)	13 Oct 2020 15:27:14

US3772041

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'VISIT3'	System	13 Oct 2020 15:27:14

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '13 Oct 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '08:28'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '13 Oct 2020 08:28'	System	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '36.5' C	(b) (4) Emily Crews (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '56'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'bpm'	System	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '15'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'breaths/min'	System	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '144'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '69'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'mmHg'	System	15 Oct 2020 16:50:30

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53

US3772041

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53

US3772041

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'No (N)'	Matthew Pohlmeier (b) (4)	13 Oct 2020 15:42:50

US3772041

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	13 Oct 2020 15:42:50

US3772041

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Oct 2020 16:51:20

US3772041

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '13 Oct 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:51:20

US3772041

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered '08:35'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:51:20

US3772041

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered '13 Oct 2020 08:35'	System	15 Oct 2020 16:51:20

US3772041

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:37:08
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	13 Oct 2020 15:27:23

US3772041

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	13 Oct 2020 15:27:23

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 64'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-14T13:39:25', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '23207e5d-457e-4116-afc3-be82e453728c' User entered 'No (N)'	System	14 Oct 2020 20:39:39
	System	14 Oct 2020 20:39:39

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-14T13:38:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '23207e5d-457e-4116-afc3-be82e453728c' User entered 'No (N)'	System	14 Oct 2020 20:39:39
	System	14 Oct 2020 20:39:39

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-14T13:39:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '23207e5d-457e-4116-afc3-be82e453728c' User entered '14 Oct 2020 13:39:36'	System	14 Oct 2020 20:39:39
	System	14 Oct 2020 20:39:39

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 71'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-20T16:33:18', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b8e156a9-40c1-40e2-ba1c-20ab7449c20f' User entered 'No (N)'	System	20 Oct 2020 23:33:35
	System	20 Oct 2020 23:33:35

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-20T16:33:25', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b8e156a9-40c1-40e2-ba1c-20ab7449c20f' User entered 'No (N)'	System	20 Oct 2020 23:33:35
	System	20 Oct 2020 23:33:35

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-20T16:33:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'b8e156a9-40c1-40e2-ba1c-20ab7449c20f' User entered '20 Oct 2020 16:33:33'	System	20 Oct 2020 23:33:35
	System	20 Oct 2020 23:33:35

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 78'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-26T16:34:59', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '793a96c8-972e-45df-a7da-24b83fb87fc0' User entered 'No (N)'	System	26 Oct 2020 23:35:15
	System	26 Oct 2020 23:35:15

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-26T16:35:04', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '793a96c8-972e-45df-a7da-24b83fb87fc0'	System	26 Oct 2020 23:35:15
User entered 'No (N)'	System	26 Oct 2020 23:35:15

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-10-26T16:35:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '793a96c8-972e-45df-a7da-24b83fb87fc0' User entered '26 Oct 2020 16:35:11'	System	26 Oct 2020 23:35:15
	System	26 Oct 2020 23:35:15

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 92'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-09T15:53:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'faabf8cd-71cc-455b-b0ef-4d0ca11abaec'	System	09 Nov 2020 23:53:59
User entered 'No (N)'	System	09 Nov 2020 23:53:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-09T15:53:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'faabf8cd-71cc-455b-b0ef-4d0ca11abaec'	System	09 Nov 2020 23:53:59
User entered 'No (N)'	System	09 Nov 2020 23:53:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-09T15:53:54', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'faabf8cd-71cc-455b-b0ef-4d0ca11abaec' User entered '09 Nov 2020 15:53:54'	System	09 Nov 2020 23:53:59
	System	09 Nov 2020 23:53:59

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered 'Day 99'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-16T08:06:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6af88c5c-31b6-435d-bded-634e5e131ac2' User entered 'No (N)'	System	16 Nov 2020 16:06:55
	System	16 Nov 2020 16:06:55

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-16T08:06:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6af88c5c-31b6-435d-bded-634e5e131ac2'	System	16 Nov 2020 16:06:55
User entered 'No (N)'	System	16 Nov 2020 16:06:55

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-16T08:06:51', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6af88c5c-31b6-435d-bded-634e5e131ac2' User entered '16 Nov 2020 08:06:51'	System	16 Nov 2020 16:06:55
	System	16 Nov 2020 16:06:55

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 18:30:58

US3772041

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:13:28
Data entry locked.	System	11 Aug 2020 18:30:58
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 18:30:58

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-23T10:57:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '45be4b44-0485-4fea-b036-705655f2cael' User entered 'No (N)'	System	23 Nov 2020 18:57:47
	System	23 Nov 2020 18:57:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-23T10:57:30', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '45be4b44-0485-4fea-b036-705655f2cae1' User entered 'No (N)'	System	23 Nov 2020 18:57:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-23T10:57:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '45be4b44-0485-4fea-b036-705655f2cael' User entered '23 Nov 2020 10:57:44'	System	23 Nov 2020 18:57:47
	System	23 Nov 2020 18:57:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-30T08:09:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd457e780-11cc-4adb-adb5-d5d98db9f3bf' User entered 'No (N)'	System	30 Nov 2020 16:09:29
	System	30 Nov 2020 16:09:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-30T08:09:16', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd457e780-11cc-4adb-adb5-d5d98db9f3bf' User entered 'No (N)'	System	30 Nov 2020 16:09:29
	System	30 Nov 2020 16:09:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-11-30T08:09:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd457e780-11cc-4adb-adb5-d5d98db9f3bf' User entered '30 Nov 2020 08:09:27'	System	30 Nov 2020 16:09:29
	System	30 Nov 2020 16:09:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-04T14:55:40', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa7a6f35-7ca5-4395-8eaf-54c1162d413b' User entered 'No (N)'	System	04 Dec 2020 22:55:53
	System	04 Dec 2020 22:55:53

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-04T14:55:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa7a6f35-7ca5-4395-8eaf-54c1162d413b'	System	04 Dec 2020 22:55:53
User entered 'No (N)'	System	04 Dec 2020 22:55:53

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-04T14:55:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'aa7a6f35-7ca5-4395-8eaf-54c1162d413b' User entered '04 Dec 2020 14:55:48'	System	04 Dec 2020 22:55:53
	System	04 Dec 2020 22:55:53

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-10T09:44:24', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '41f97e04-b007-4eb2-aa80-219cbf317ae7' User entered 'No (N)'	System	10 Dec 2020 17:44:34
	System	10 Dec 2020 17:44:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-10T09:44:27', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '41f97e04-b007-4eb2-aa80-219cbf317ae7' User entered 'No (N)'	System	10 Dec 2020 17:44:34
	System	10 Dec 2020 17:44:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-10T09:44:32', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '41f97e04-b007-4eb2-aa80-219cbf317ae7' User entered '10 Dec 2020 09:44:32'	System	10 Dec 2020 17:44:34
	System	10 Dec 2020 17:44:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-17T10:09:33', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ddd35249-c574-45a9-b74c-8f99f93d8eeb' User entered 'No (N)'	System	17 Dec 2020 18:09:50
	System	17 Dec 2020 18:09:50

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-17T10:09:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ddd35249-c574-45a9-b74c-8f99f93d8eeb'	System	17 Dec 2020 18:09:50
User entered 'No (N)'	System	17 Dec 2020 18:09:50

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-17T10:09:48', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ddd35249-c574-45a9-b74c-8f99f93d8eeb' User entered '17 Dec 2020 10:09:48'	System	17 Dec 2020 18:09:50
	System	17 Dec 2020 18:09:50

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-28T12:07:12', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6aabde12-d6b8-4111-a459-b38f158bc9fe' User entered 'No (N)'	System	28 Dec 2020 20:07:21
	System	28 Dec 2020 20:07:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-28T12:07:14', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6aabde12-d6b8-4111-a459-b38f158bc9fe' User entered 'No (N)'	System	28 Dec 2020 20:07:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-28T12:07:19', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6aabde12-d6b8-4111-a459-b38f158bc9fe' User entered '28 Dec 2020 12:07:19'	System	28 Dec 2020 20:07:21
	System	28 Dec 2020 20:07:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-31T10:00:04', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '36e973fd-bf40-4f17-bbe6-033b30e2176a' User entered 'No (N)'	System	31 Dec 2020 18:00:24
	System	31 Dec 2020 18:00:24

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-31T10:00:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '36e973fd-bf40-4f17-bbe6-033b30e2176a' User entered 'No (N)'	System	31 Dec 2020 18:00:24

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2020-12-31T10:00:22', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '36e973fd-bf40-4f17-bbe6-033b30e2176a' User entered '31 Dec 2020 10:00:22'	System	31 Dec 2020 18:00:24
	System	31 Dec 2020 18:00:24

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-07T14:04:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3cc67258-2bcd-430e-aaf2-40e899be2837'	System	07 Jan 2021 22:04:58
User entered 'No (N)'	System	07 Jan 2021 22:04:58

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-07T14:04:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3cc67258-2bcd-430e-aaf2-40e899be2837'	System	07 Jan 2021 22:04:58
User entered 'No (N)'	System	07 Jan 2021 22:04:58

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-07T14:04:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3cc67258-2bcd-430e-aaf2-40e899be2837' User entered '07 Jan 2021 14:04:56'	System	07 Jan 2021 22:04:58
	System	07 Jan 2021 22:04:58

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-14T14:08:13', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6fd83671-0e99-4627-b3d4-6f6c9cdbbb7f' User entered 'No (N)'	System	14 Jan 2021 22:08:22
	System	14 Jan 2021 22:08:22

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-14T14:08:15', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6fd83671-0e99-4627-b3d4-6f6c9cdbbb7f' User entered 'No (N)'	System	14 Jan 2021 22:08:22

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-14T14:08:19', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '6fd83671-0e99-4627-b3d4-6f6c9cdbbb7f' User entered '14 Jan 2021 14:08:19'	System	14 Jan 2021 22:08:22

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-21T13:13:13', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3d94d8c2-043e-463b-801d-f39afb057a3c' User entered 'No (N)'	System	21 Jan 2021 21:14:15
	System	21 Jan 2021 21:14:15

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-21T13:14:03', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3d94d8c2-043e-463b-801d-f39afb057a3c'	System	21 Jan 2021 21:14:15
User entered 'No (N)'	System	21 Jan 2021 21:14:15

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-21T13:14:11', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '3d94d8c2-043e-463b-801d-f39afb057a3c' User entered '21 Jan 2021 13:14:11'	System	21 Jan 2021 21:14:15
	System	21 Jan 2021 21:14:15

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-28T13:37:44', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd8185355-3e7d-429f-bb82-9c8551741b57'	System	28 Jan 2021 21:37:59
User entered 'No (N)'	System	28 Jan 2021 21:37:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-28T13:37:49', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd8185355-3e7d-429f-bb82-9c8551741b57'	System	28 Jan 2021 21:37:59
User entered 'No (N)'	System	28 Jan 2021 21:37:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-01-28T13:37:56', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'd8185355-3e7d-429f-bb82-9c8551741b57'	System	28 Jan 2021 21:37:59
User entered '28 Jan 2021 13:37:56'	System	28 Jan 2021 21:37:59

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-04T13:37:36', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '277e21b0-ea1e-4cbd-b14e-40751b7d7657' User entered 'No (N)'	System	04 Feb 2021 21:37:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-04T13:37:38', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '277e21b0-ea1e-4cbd-b14e-40751b7d7657' User entered 'No (N)'	System	04 Feb 2021 21:37:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-04T13:37:43', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '277e21b0-ea1e-4cbd-b14e-40751b7d7657' User entered '04 Feb 2021 13:37:43'	System	04 Feb 2021 21:37:47
	System	04 Feb 2021 21:37:47

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-11T13:29:37', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cea57286-8776-43c2-97da-4c91239cca57' User entered 'No (N)'	System	11 Feb 2021 21:29:52
	System	11 Feb 2021 21:29:52

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-11T13:29:46', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cea57286-8776-43c2-97da-4c91239cca57' User entered 'No (N)'	System	11 Feb 2021 21:29:52

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-11T13:29:50', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'cea57286-8776-43c2-97da-4c91239cca57' User entered '11 Feb 2021 13:29:50'	System	11 Feb 2021 21:29:52
	System	11 Feb 2021 21:29:52

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-18T14:25:58', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '09225aa0-3574-4041-91cb-ffa3554eeb02'	System	18 Feb 2021 22:26:45
User entered 'Yes (Y)'	System	18 Feb 2021 22:26:45

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-18T14:26:03', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '09225aa0-3574-4041-91cb-ffa3554eeb02'	System	18 Feb 2021 22:26:45
User entered 'No (N)'	System	18 Feb 2021 22:26:45

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-18T14:26:09', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '09225aa0-3574-4041-91cb-ffa3554eeb02' User entered 'No (N)'	System	18 Feb 2021 22:26:45

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-18T14:26:29', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '09225aa0-3574-4041-91cb-ffa3554eeb02' User entered 'No (N)'	System	18 Feb 2021 22:26:45
	System	18 Feb 2021 22:26:45

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-18T14:26:41', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '09225aa0-3574-4041-91cb-ffa3554eeb02' User entered '18 Feb 2021 14:26:41'	System	18 Feb 2021 22:26:45
	System	18 Feb 2021 22:26:45

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-25T14:21:37-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '76760f30-90d8-4a25-9675-8bc4f6f6c289' User entered 'No (N)'	System	26 Feb 2021 05:33:34
	System	26 Feb 2021 05:33:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-25T14:21:41-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '76760f30-90d8-4a25-9675-8bc4f6f6c289' User entered 'No (N)'	System	26 Feb 2021 05:33:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-02-25T14:21:48-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '76760f30-90d8-4a25-9675-8bc4f6f6c289' User entered '25 Feb 2021 22:21:48'	System	26 Feb 2021 05:33:34
	System	26 Feb 2021 05:33:34

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-04T14:15:30-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ec3b030f-cdd5-4843-87ad-5562e996d74a' User entered 'No (N)'	System	04 Mar 2021 22:15:41
	System	04 Mar 2021 22:15:41

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-04T14:15:32-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ec3b030f-cdd5-4843-87ad-5562e996d74a'	System	04 Mar 2021 22:15:41
User entered 'No (N)'	System	04 Mar 2021 22:15:41

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-04T14:15:37-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ec3b030f-cdd5-4843-87ad-5562e996d74a' User entered '04 Mar 2021 14:15:37'	System	04 Mar 2021 22:15:41
	System	04 Mar 2021 22:15:41

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-11T13:27:04-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '32c765c9-9d60-4ca9-83b2-1a1880a443a3'	System	11 Mar 2021 21:27:21
User entered 'No (N)'	System	11 Mar 2021 21:27:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-11T13:27:12-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '32c765c9-9d60-4ca9-83b2-1a1880a443a3'	System	11 Mar 2021 21:27:21
User entered 'No (N)'	System	11 Mar 2021 21:27:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-11T13:27:17-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '32c765c9-9d60-4ca9-83b2-1a1880a443a3' User entered '11 Mar 2021 13:27:17'	System	11 Mar 2021 21:27:21
	System	11 Mar 2021 21:27:21

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-18T14:11:21-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7ac3459a-f33f-4b5b-8395-efd68ed127d1'	System	18 Mar 2021 21:11:35
User entered 'No (N)'	System	18 Mar 2021 21:11:35

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-18T14:11:26-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7ac3459a-f33f-4b5b-8395-efd68ed127d1'	System	18 Mar 2021 21:11:35
User entered 'No (N)'	System	18 Mar 2021 21:11:35

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-18T14:11:33-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '7ac3459a-f33f-4b5b-8395-efd68ed127d1'	System	18 Mar 2021 21:11:35
User entered '18 Mar 2021 14:11:33'	System	18 Mar 2021 21:11:35

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-25T14:34:16-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'dac01915-999d-476c-91d9-114359603b83'	System	25 Mar 2021 21:34:39
User entered 'No (N)'	System	25 Mar 2021 21:34:39

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-25T14:34:28-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'dac01915-999d-476c-91d9-114359603b83'	System	25 Mar 2021 21:34:39
User entered 'No (N)'	System	25 Mar 2021 21:34:39

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-25T14:34:33-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'dac01915-999d-476c-91d9-114359603b83'	System	25 Mar 2021 21:34:39
User entered '25 Mar 2021 14:34:33'	System	25 Mar 2021 21:34:39

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-01T15:06:04-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '26929ff7-364d-491c-adce-88f726411582'	System	01 Apr 2021 22:09:56
User entered 'No (N)'	System	01 Apr 2021 22:09:56

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-01T15:06:11-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '26929ff7-364d-491c-adce-88f726411582'	System	01 Apr 2021 22:09:56
User entered 'No (N)'	System	01 Apr 2021 22:09:56

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-01T15:06:23-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '26929ff7-364d-491c-adce-88f726411582'	System	01 Apr 2021 22:09:56
User entered '01 Apr 2021 15:06:23'	System	01 Apr 2021 22:09:56

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-08T13:02:24-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a2d958bc-54a8-4ba2-b551-cb88b1769fae' User entered 'No (N)'	System	08 Apr 2021 20:02:54
	System	08 Apr 2021 20:02:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-08T13:02:38-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a2d958bc-54a8-4ba2-b551-cb88b1769fae' User entered 'No (N)'	System	08 Apr 2021 20:02:54
	System	08 Apr 2021 20:02:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-08T13:02:44-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'a2d958bc-54a8-4ba2-b551-cb88b1769fae' User entered '08 Apr 2021 13:02:44'	System	08 Apr 2021 20:02:54
	System	08 Apr 2021 20:02:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-15T14:20:04-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '65196875-cc98-486c-b89c-fc0140a51beb' User entered 'No (N)'	System	15 Apr 2021 21:20:20
	System	15 Apr 2021 21:20:20

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-15T14:20:10-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '65196875-cc98-486c-b89c-fc0140a51beb' User entered 'No (N)'	System	15 Apr 2021 21:20:20
	System	15 Apr 2021 21:20:20

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-15T14:20:16-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '65196875-cc98-486c-b89c-fc0140a51beb' User entered '15 Apr 2021 14:20:16'	System	15 Apr 2021 21:20:20
	System	15 Apr 2021 21:20:20

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-22T13:54:06-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '500469dd-9450-482c-b587-9862af2182b6'	System	22 Apr 2021 20:54:29
User entered 'No (N)'	System	22 Apr 2021 20:54:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-22T13:54:12-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '500469dd-9450-482c-b587-9862af2182b6'	System	22 Apr 2021 20:54:29
User entered 'No (N)'	System	22 Apr 2021 20:54:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-22T13:54:25-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '500469dd-9450-482c-b587-9862af2182b6'	System	22 Apr 2021 20:54:29
User entered '22 Apr 2021 13:54:25'	System	22 Apr 2021 20:54:29

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-29T13:41:42-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ac00a072-ddf6-48ad-acfd-42592216cec1'	System	29 Apr 2021 20:41:54
User entered 'No (N)'	System	29 Apr 2021 20:41:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

Have you been exposed to someone with 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 (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-29T13:41:46-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ac00a072-ddf6-48ad-acfd-42592216cec1'	System	29 Apr 2021 20:41:54
User entered 'No (N)'	System	29 Apr 2021 20:41:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-04-29T13:41:50-07:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: 'ac00a072-ddf6-48ad-acfd-42592216cec1' User entered '29 Apr 2021 13:41:50'	System	29 Apr 2021 20:41:54
	System	29 Apr 2021 20:41:54

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:53:36

US3772041

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:48:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:53:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:53:36

US3772041

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:08

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)	30 Apr 2021 19:14:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-04T14:15:13-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '898bb4e2-6b24-49eb-a56e-dfcbee1be3de'	System	04 Mar 2021 22:15:22
User entered 'No (N)'	System	04 Mar 2021 22:15:22

US3772041

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:48:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:14:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AFEE8981-E214-4D83-BCC8-B95DE89F5792)', Time: '2021-03-04T14:15:20-08:00', User OID: 'PatientReportedOutcome (US3772041)', ODM File OID: '898bb4e2-6b24-49eb-a56e-dfcbee1be3de' User entered '04 Mar 2021 14:15:20'	System	04 Mar 2021 22:15:22
	System	04 Mar 2021 22:15:22

US3772041

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:02:42

US3772041

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:02:42

US3772041

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:02:42

US3772041

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:02:42

US3772041

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 00:25:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 23:02:46

US3772041

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:26:53
User entered 'I'	System	04 Dec 2020 23:02:46

US3772041

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 23:02:56

US3772041

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:56
User entered '4 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 23:02:56

US3772041

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Dec 2020 23:02:56

US3772041

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:00:56
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 23:02:56

US3772041

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 20:01:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 23:03:01

US3772041

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered 'I'	System	04 Dec 2020 23:03:01

US3772041

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Jan 2021 21:45:05

US3772041

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '4 Jan 2021'	(b) (4) Matthew Pohlmeier (b) (4)	04 Jan 2021 21:45:05

US3772041

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeyer (b) (4)	04 Jan 2021 21:45:05

US3772041

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	04 Jan 2021 21:45:05

US3772041

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	04 Jan 2021 21:45:11

US3772041

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered 'I'	System	04 Jan 2021 21:45:11

US3772041

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:59:49

US3772041

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '2 Feb 2021'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:59:49

US3772041

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:59:49

US3772041

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:59:49

US3772041

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	02 Feb 2021 22:59:55

US3772041

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:23:41
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered 'I'	System	02 Feb 2021 22:59:55

US3772041

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:03
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:22

US3772041

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:03
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '17 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:22

US3772041

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:03
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Clinic (Clinic)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:22

US3772041

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered 'VISIT4'	System	17 Mar 2021 16:06:22

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
User entered empty.	System	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered empty.	System	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered empty.	System	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered empty.	System	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:08
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:31:30
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered empty.	System	01 Apr 2021 21:25:03

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37

US3772041

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:48:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:34
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37

US3772041

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:13
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'No (N)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:30

US3772041

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:48:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:13
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:30

US3772041

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:51

US3772041

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '17 Mar 2021'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:51

US3772041

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '08:25'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:51

US3772041

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
User entered '17 Mar 2021 08:25'	System	17 Mar 2021 16:06:51

US3772041

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 18:36:25
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4) (b) (4)	17 Mar 2021 16:06:57

US3772041

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:28:14
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:17:37
User entered 'I'	System	17 Mar 2021 16:06:57

US3772041

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:52:02

US3772041

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '7 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:52:02

US3772041

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:52:02

US3772041

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:52:02

US3772041

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:52:14

US3772041

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Apr 2021 15:52:14

US3772041

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:25:43

US3772041

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:41
User entered '3 May 2021'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:25:43

US3772041

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:25:43

US3772041

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:48:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:41
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:25:43

US3772041

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:25:49

US3772041

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:48:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:25:49

US3772041

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:32

US3772041

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:32

US3772041

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[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 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:32

US3772041

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

Form: Visit Date

Generated On: 10 Jun 2021 09:48:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 22:00:32

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:54

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:13:54

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 11:40:11
User entered 'mRNA-1273 (mRNA-1273)'	Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:40:11
User entered 'mRNA-1273 (mRNA-1273)'	Emily Crews (b) (4)	14 Jan 2021 22:00:49
	(b) (4)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User entered empty.	System	14 Jan 2021 22:00:49

US3772041

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

Form: Unblinding

Generated On: 10 Jun 2021 09:48:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User entered empty.	System	14 Jan 2021 22:00:49

US3772041

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:54:13
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'Stored onsite' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Feb 2021 16:08:56
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:23:42
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:58

US3772041

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:58

US3772041

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '10:05'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:00:58

US3772041

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User entered '14 Jan 2021 10:05'	System	14 Jan 2021 22:00:58

US3772041

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:01:07

US3772041

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:01:07

US3772041

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '10:03'	(b) (4) Emily Crews (b) (4) (b) (4)	14 Jan 2021 22:01:07

US3772041

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:53
User entered '14 Jan 2021 10:03'	System	14 Jan 2021 22:01:07

US3772041

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:48:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:16
User signature succeeded.	Jamshid Saleh (b) (4)	13 Mar 2021 01:13:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Sarah Sandberg (b) (4)	17 Feb 2021 17:38:25
User entered 'No (N)'	(b) (4)	
	Emily Crews (b) (4)	06 Oct 2020 23:15:03
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:46
User entered 'USA-US107-2021-mRNA-1273-P301000011'	System	18 Feb 2021 14:45:43
User entered 'New'	(b) (4), (b) (6)	18 Feb 2021 14:45:43

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
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.	(b) (4) Coder Import (b) (4)	17 Feb 2021 17:43:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 17:43:03
Data point term sent to Coder	System	17 Feb 2021 17:42:27
User entered 'Exacerbation of Hypertension'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '15 Feb 2021'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '16 Feb 2021'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 19:01:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 19:00:12
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'I'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '15 Feb 2021'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:27:28
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Medical records have been requested 4 times. Site will submit records when they are received' (Site from Safety).	Emily Crews (b) (4) (b) (4)	15 Mar 2021 19:29:17
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 01:31:51
User entered '16 Feb 2021'	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Not Related (NOT RELATED)'	(b) (4) Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'I'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:41:40
	(b) (4)	

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'PV Query: Is chest pain symptom of the event exacerbation of hypertension? If yes then please consider updating the event onset date to 14 Feb 2021, when first signs and symptoms appeared. If No, then kindly report chest pain as separate SAE/AE..' (Site from Safety). Query 'PV Query: Is chest pain symptom of the event exacerbation of hypertension? If yes then please consider updating the event onset date to 14 Feb 2021, when first signs and symptoms appeared. If No, then kindly report chest pain as separate SAE/AE..' answered with 'Per medical records, the chest pain noted on 14 Feb only lasted a couple hours and the subject woke up the following day feeling fine and was able to exercise. Subject began experiencing chest pain again on 15 Feb 2021. Per PI the start date of this SAE does not need to be changed. Per protocol AEs are no longer reported unless it becomes an SAE or MAAE since the chest pain began and resolved in 14 Feb 2021 this does not need to be reported as an AE ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 16:31:50
User opened query 'PV Query: Is chest pain symptom of the event exacerbation of hypertension? If yes then please consider updating the event onset date to 14 Feb 2021, when first signs and symptoms appeared. If No, then kindly report chest pain as separate SAE/AE..' (Site from Safety).	Emily Crews (b) (4)	14 Apr 2021 19:28:47
User opened query 'PV Query: Is chest pain symptom of the event exacerbation of hypertension? If yes then please consider updating the event onset date to 14 Feb 2021, when first signs and symptoms appeared. If No, then kindly report chest pain as separate SAE/AE..' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 00:39:44
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) (6)	06 Apr 2021 13:41:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Narrative](#)

Audit	User	Time (GMT)
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 'records have been emailed to the provided email' (Site from Safety).	Emily Crews (b) (4) (b) (4)	05 Apr 2021 19:03:18
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. ***Please leave query unanswered until information is available.***' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 15:13:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ***Please leave query unanswered until information is available.***' answered with 'No report of COVID testing in medical records' (Site from Safety).	Emily Crews (b) (4) (b) (4)	29 Mar 2021 17:22:39
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 Mar 2021 16:23:44
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. ***Please leave query unanswered until information is available.***' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 16:23:36

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (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 Mar 2021 14:44:06
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:44:03
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 14:43:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (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 'Site has not received records will update SAE when they are available' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Mar 2021 21:17:52
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Site has not received records will update SAE when they are available' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Mar 2021 21:17:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Site has not received records will update SAE when they are available' (Site from Safety).	Emily Crews (b) (4) (b) (4)	18 Mar 2021 21:17:43
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 17:28:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 01:31:26
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)	26 Feb 2021 01:30:56
User entered 'Subject called the site yesterday 16Feb2021 at 16:20 and reported that she went to the ER with a chief complaint of chest pain. She was admitted on 15Feb2021. She reported being discharge as having an exacerbation of HTN and was prescribed a new HTN med. Records were requested'	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 17:41:40

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:04:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 18:04:01
Data point term sent to Coder	System	17 Feb 2021 18:03:10
User entered 'Hyperlipidemia'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '15 Feb 2021'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered empty.	System	17 Feb 2021 18:02:15

US3772041

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)' reason for change: New Information	Ruba Zanaid (b) (4)	05 Apr 2021 18:55:52
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '16 Mar 2021' reason for change: New Information	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 18:55:52
User entered empty.	(b) (4) Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered empty.	System	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Grade 1/Mild (Grade 1/Mild)'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 18:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:02:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 18:02:15
User entered empty.	System	17 Feb 2021 18:02:15
	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 18:02:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Feb 2021 18:02:31
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Feb 2021 18:02:15
User entered empty.	System	17 Feb 2021 18:02:15
	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15
	(b) (4)	

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Generated On: 10 Jun 2021 09:48:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'None (NONE)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:48:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	04 Mar 2021 18:06:51
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	17 Feb 2021 18:02:31
User entered '1' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:31
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	17 Feb 2021 18:02:15
User entered '0'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '1' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	04 Mar 2021 18:06:51
User entered '0'	(b) (4) Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 18:56:06
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 18:55:52
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Ruba Zanaid (b) (4) (b) (4)	17 Feb 2021 18:02:15

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	05 Apr 2021 18:56:06
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	05 Apr 2021 18:55:52
User entered empty.	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'SUBJECT CALLED OUR SITE TO REPORT THEIR ADMISSION TO THE HOSPITAL ON 15-FEB-2021 DUE TO EXACERBATION OF THEIR HYPERTENSION WHICH WAS DOCUMENTED ON A SEPARATE SAE LOG. SUBJECT REPORTED HYPERLIPIDEMIA AS A SUB DIAGNOSIS DURING THEIR HOSPITAL VISIT. OUR SITE REQUESTED MEDICAL RECORDS. On an unscheduled call to the subject after receipt of their medical records on 29Mar2021, subject reported a resolution of their Hyperlipidemia on 16Mar2021.' reason for change: New Information	Ruba Zanaid (b) (4)	05 Apr 2021 18:55:52
User entered 'Subject called our site to report their admission to the hospital on 15-Feb-2021 due to exacerbation of their hypertension which was documented on a separate SAE log. Subject reported hyperlipidemia as a sub diagnosis during their hospital visit. Our site requested medical records'	Ruba Zanaid (b) (4)	17 Feb 2021 18:02:15

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered '0'	System	17 Feb 2021 18:02:15

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Folder: Adverse Events

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered '1'	System	17 Feb 2021 18:02:15

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09

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Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension exacerbated - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 00:22:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 00:22:57
Data point term sent to Coder	System	12 Mar 2021 00:22:11
User entered 'Exacerbation of Hypertension'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '8 Mar 2021'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered empty.	System	12 Mar 2021 00:21:38

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '10 Mar 2021'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered empty.	System	12 Mar 2021 00:21:38

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 00:22:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:22:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:21:38
User entered empty.	System	12 Mar 2021 00:21:38
	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 00:22:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:22:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:21:38
User entered empty.	System	12 Mar 2021 00:21:38
	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:22:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Mar 2021 00:22:08
User entered 'None (NONE)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:22:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	12 Mar 2021 00:21:38
User entered empty.	System	12 Mar 2021 00:21:38
	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 00:22:21
User entered '0' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:22:21
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 00:21:38
User entered '1'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'I'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

US3772041

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:21:38

US3772041

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Subject called the site today reporting that they went to the ER on Monday 08Mar2021 feeling high heartbeat and having higher blood pressure. Subject was not admitted to the hospital and went home , their doctor increased the dose of their Lisinopril as a result.'	(b) (4) Ruba Zanaid (b) (4)	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered '0'	System	12 Mar 2021 00:21:38

US3772041

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09
User entered '1'	System	12 Mar 2021 00:21:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:47:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:48:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:16
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:40:44

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 18:42:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 18:42:21
	(b) (4)	
Data point term sent to Coder User entered 'Metoprolol'	System	11 Aug 2020 18:41:49
	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Hypertension'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
Signature has been broken.	Ruba Zanaid (b) (4)	05 Apr 2021 22:16:23
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '50'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'mg (mg)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'once daily (QD)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
Signature has been broken.	Ruba Zanaid (b) (4)	05 Apr 2021 22:16:31
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Oral (ORAL)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User closed query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of HYPERTENSION. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:08:44
Query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of HYPERTENSION. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:15:18
User opened query 'Per DM CLR: The Con Med start date is prior to the start date of the corresponding Medical History condition of HYPERTENSION. Please reconcile Con Med and Med History Start dates and update applicable eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 06:06:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 18:09:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:41:35
User entered 'un UNK 2017'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:41:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	17 Feb 2021 17:42:40
	(b) (4)	
User entered 'Yes (Y)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	17 Feb 2021 17:42:40
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Emily Crews (b) (4)	11 Aug 2020 18:41:35
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User entered '1'	System	11 Aug 2020 18:41:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User entered '1'	System	11 Aug 2020 18:41:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:05
User entered '804 (804)'	System	11 Aug 2020 18:41:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Aug 2020 18:44:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 18:44:25
Data point term sent to Coder	System	11 Aug 2020 18:42:50
User entered 'Synthroid'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Emily Crews (b) (4)	11 Aug 2020 18:42:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User closed query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM). Query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:08:49
User opened query 'Per DM CLR: Note there is no Medical History Condition that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate medical history eCRF.' (Site from DM). User entered 'Hypothyroidism'	Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:14:31
	(b) (4), (b) (6)	02 Oct 2020 06:07:38
	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '75'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'ug (ug)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'once daily (QD)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 18:10:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 18:42:11
User entered 'un UNK 2015'	Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 18:42:11

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
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)	17 Feb 2021 17:46:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 17:46:02
	(b) (4)	
Data point term sent to Coder	System	17 Feb 2021 17:45:34
User entered 'Influenza Vaccine'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Influenza Prophylaxis'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0.5'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'mL (mL)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'once (ONCE)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '13 Oct 2020'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '13 Oct 2020'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:44:37
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User entered empty.	System	17 Feb 2021 17:44:37

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User entered empty.	System	17 Feb 2021 17:44:37

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:11
User entered empty.	System	17 Feb 2021 17:44:37

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
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)	17 Feb 2021 17:44:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 17:44:01
	(b) (4)	
Data point term sent to Coder User entered 'Lisinopril'	System	17 Feb 2021 17:43:29
	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Hypertension'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '5'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'mg (mg)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'once daily (QD)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Oral (ORAL)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '16 Feb 2021'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:23:15
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '10 Mar 2021' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	12 Mar 2021 00:23:15
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:18
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User entered '1'	System	17 Feb 2021 17:43:18

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User entered '1'	System	17 Feb 2021 17:43:18

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:17
User entered '804 (804)'	System	17 Feb 2021 17:43:18

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User closed query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:30:39
' (Site from DM).		
Query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	Emily Crews (b) (4) (b) (4)	04 Mar 2021 18:07:13
' answered with 'Updated AE log' (Site from DM).		
User opened query 'Per DM CLR: This Conmed is given for the AE#2. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.	(b) (4), (b) (6)	04 Mar 2021 05:02:42
' (Site from DM).		
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 17:45:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 17:45:01
Data point term sent to Coder	System	17 Feb 2021 17:44:33
User entered 'Atorvastatin'	Sarah Sandberg (b) (4) (b) (4)	17 Feb 2021 17:43:51

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Hyperlipidemia'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '20'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'mg (mg)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'once daily (QD)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Oral (ORAL)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '16 Feb 2021'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
Signature has been broken.	Ruba Zanaid (b) (4)	05 Apr 2021 19:15:05
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Ruba Zanaid (b) (4)	05 Apr 2021 19:15:05
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
Signature has been broken.	Ruba Zanaid (b) (4)	05 Apr 2021 19:15:05
	(b) (4)	
User entered '16 Mar 2021' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	05 Apr 2021 19:15:05
	(b) (4)	
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Sarah Sandberg (b) (4)	17 Feb 2021 17:43:51
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User entered '1'	System	17 Feb 2021 17:43:51

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User entered '1'	System	17 Feb 2021 17:43:51

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:46:22
User entered '804 (804)'	System	17 Feb 2021 17:43:51

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Mar 2021 00:27:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 00:27:57
Data point term sent to Coder	System	12 Mar 2021 00:27:13
User entered 'Lisinopril'	Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'No (N)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Exacerbation of Hypertension'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '10'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'mg (mg)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'twice daily (BID)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered 'Oral (ORAL)'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '10 Mar 2021'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered '0'	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4)	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 00:26:30

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE SODIUM PHOSPHATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 04:04:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:04:40
Data point term sent to Coder	System	05 Apr 2021 19:29:58
User entered 'Prednisolone Sodium Phosphate 1%'	Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:30:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 19:30:03
User entered 'No (N)' reason for change: Data Entry Error	Ruba Zanaid (b) (4)	05 Apr 2021 19:30:03
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 19:29:46
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Cornea Transplant . Right eye.'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '1'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Other (OTHER)'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'drop'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'once daily (QD)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'UN Jan 2020'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:29:46

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 03:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 03:55:39
Data point term sent to Coder	System	05 Apr 2021 19:33:01
User entered 'Timolol Maleate 0.5%'	Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
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	05 Apr 2021 19:32:15
User entered 'No (N)' reason for change: Data Entry Error	System	05 Apr 2021 19:32:15
User opened query 'Data is required. Please complete.' (Site from System).	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:15
User entered empty.	(b) (4)	
	System	05 Apr 2021 19:32:06
	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Glaucoma Right Eye'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '1'	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Other (OTHER)'	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'drop'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'once daily (QD)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

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

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'UN UNK 1990'	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered '0'	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered 'Yes (Y)'	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
	(b) (4)	
User entered empty.	Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4) Ruba Zanaid (b) (4)	05 Apr 2021 19:32:06
	(b) (4)	

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:48:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 19:32:06

US3772041

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:48:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:53:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	06 Oct 2020 23:14:59

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'USA-US107-2021-MRNA-1273-P301000011'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Jamshid'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Saleh'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '3652 Eureka Way'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Redding'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '96001'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:41:44
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
User entered 'US'	(b) (4) System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 13:42:01
User entered '1'	System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'USA-US107-2021-MRNA-1273-P301000011'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Jamshid'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Saleh'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '3652 Eureka Way'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Redding'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '96001'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:41:44
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
User entered 'US'	(b) (4) System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 13:42:01
User entered '1'	System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
User entered '18/Feb/2021 09:46'	(b) (4) System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:48:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:41:44
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'USA-US107-2021-MRNA-1273-P301000011'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Yes (Y)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'No (N)'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Jamshid'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Saleh'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '3652 Eureka Way'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered 'Redding'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 14:45:58
User entered '96001'	System	18 Feb 2021 14:45:43

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 13:41:44
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:15
User entered 'US'	(b) (4) System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:48:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 13:42:01
User entered '1'	System	18 Feb 2021 14:46:05

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered '06/Apr/2021 13:41'	(b) (4) System	06 Apr 2021 13:42:01

US3772041

Folder: SAE USA-US107-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:48:08

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:45:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:42:01